IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

R.J. REYNOLDS TOBACCO COMPANY; SANTA FE NATURAL TOBACCO COMPANY, INC.; ITG BRANDS, LLC; LIGGETT GROUP LLC; NEOCOM, INC.; RANGILA ENTERPRISES INC.; RANGILA LLC; SAHIL ISMAIL, INC.; and IS LIKE YOU INC.; *Plaintiffs*, *v.* UNITED STATES FOOD AND DRUG ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEPHEN M. HAHN, in his official capacity as Commissioner of the United States Food and Drug Administration; and ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; *Defendants.*	CIVIL ACTION NO. 6:20-cv-00176

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND
A PRELIMINARY INJUNCTION

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INTRODUCTION

For nearly fifty-five years, cigarette packages have included textual warnings that convey straightforward factual information about the risks of smoking. Today there is effectively universal awareness that smoking poses health risks—a message that has been repeatedly communicated to the public from numerous sources for decades. In 2009, however, Congress transformed cigarette warnings from factual disclosures to government-mandated anti-smoking advocacy. Specifically, Congress instructed the Food and Drug Administration ("FDA" or "the Agency") to issue regulations that require massive "color graphics depicting the negative health consequences of smoking." Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 201(a), 123 Stat. 1776, 1845 (2009) (codified at 15 U.S.C. § 1333(d)[1]).[1] In 2011, FDA did so, but before the regulation took effect, the D.C. Circuit held that it violated the First Amendment. FDA has now issued a second graphic-warnings regulation. *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 85 Fed. Reg. 15,638 (Mar. 18, 2020) ("the Rule"). It too is invalid.

The Rule requires the use of eleven new textual warnings, accompanied by eleven graphic images—including a specimen cup filled with bloody urine and a pair of diseased feet with several amputated toes—that are designed to frighten, shock, and disgust adult cigarette consumers. These "warnings" must occupy the entire top 50% of the front *and* back of cigarette packages and the top 20% of cigarette advertising. These requirements clearly cross the line into anti-smoking advocacy.

Such warnings are unprecedented. Never before in the United States have producers of a lawful product been required to use their own packages and advertising to convey an emotionally charged government message urging adult consumers to shun their products. Far from conveying

[1] Two separate provisions of the Tobacco Control Act were codified as 15 U.S.C. § 1333(d). To avoid confusion, this Motion will refer to those provisions as Sections 201(a) and 202(b) of the Tobacco Control Act and will cite to those provisions as § 1333(d)[1] and § 1333(d)[2], based on the order in which they appear in the statute.

purely factual and uncontroversial statements about the risks of smoking, these requirements force Plaintiffs to become a mouthpiece for the government's anti-smoking advocacy.

This is precisely the type of compelled speech that the First Amendment prohibits. The government may not compel Plaintiffs to "use their private property as a 'mobile billboard' for the State's ideological message." *Wooley v. Maynard*, 430 U.S. 705, 715 (1977). Nor may the government use compelled disclosures to drown out commercial speech regarding lawful products that it does not like. "The State can express [its] view through its own speech. But a State's failure to persuade does not allow it to hamstring the opposition. The State may not burden the speech of others in order to tilt public debate in a preferred direction." *Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 578–79 (2011).

The new graphic warnings are also misleading. The comments in the administrative record show that the warnings communicate inaccurate messages about the consequences of smoking. And this is borne out by FDA's own studies, which reveal that study participants were consistently confused and misled by the warnings.

When FDA first tried, in the words of the then-FDA Commissioner, to transform cigarette packages and advertising into "mini billboard[s]" for the government's anti-smoking message, the D.C. Circuit held that the rule violated the First Amendment. *See R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1212 & n.6 (D.C. Cir. 2012) (quoting FDA, *Tobacco Strategy Announcement* (Nov. 10, 2010)), *overruled in part by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 31 (D.C. Cir. 2014) (en banc). The court recognized that FDA's "warnings" were not "factual" disclosures; rather, they were "unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting." *Id.* at 1217. The court also recognized that the "warnings" were not "uncontroversial"; instead, "many of the images chosen by FDA could be misinterpreted by consumers." *Id.* at 1216. And the court held that "FDA has not provided a shred of evidence … showing that the graphic warnings will 'directly advance' its interest in reducing the number of Americans who smoke." *Id.* at 1219.

FDA's new rule fares no better. Once again, the Rule is an unconstitutional attempt to compel Plaintiffs to disparage their own products, frighten and shame their own customers, and proclaim the government's "billboard"-style anti-smoking messages. Once again, the warning images (and now also the text) would mislead consumers about the risks of smoking. And this time, FDA does not even attempt to prove the Rule will change consumers' smoking behavior. Thus, FDA effectively concedes that the graphic warnings will achieve nothing in terms of improving public health. FDA makes the weaker claim that the Rule will improve the public's understanding of smoking risks. But the government has no substantial interest in improving the public's understanding for its own sake, without any accompanying change in behavior. In any event, in light of effectively universal public awareness of the harms of smoking, FDA cannot show the Rule will meaningfully advance even that supposed interest. Thus, in light of the images, text, size, and placement of the new warnings, each of the eleven warnings is unlawful and the Rule should be vacated in its entirety.[2]

FDA's back-to-back failures to develop a constitutional rule reveal a larger problem: the Tobacco Control Act's graphic-warnings mandate is itself unconstitutional. Given the Act's directive, FDA will undoubtedly issue a third graphic-warnings rule if this one is invalidated, and that rule will

[2] Even if the Court were to find the warnings unlawful only in part, it should still vacate the entire Rule. *R.J. Reynolds*, 696 F.3d at 1211, 1222 (vacating entire graphic warnings rule without separately considering validity of textual warnings). "[P]artial affirmance" of a regulation "is not an option when … there is substantial doubt that the agency would have adopted the severed portion on its own." *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1028 (D.C. Cir. 2000) (internal quotation marks omitted). Here, the various warnings and elements of the warnings are sufficiently "intertwined" with each other that there is no reason to be confident that FDA would have adopted any different version of the Rule. *Id.*; *see also, e.g., Chamber of Commerce v. U.S. Dep't of Labor*, 885 F.3d 360, 388 (5th Cir. 2018) ("th[e] comprehensive regulatory package is plainly not amenable to severance"). Moreover, severance is appropriate only if the severed rule could "sensibly serve the goals for which it was designed." *MD/DC/DE Broadcasters Ass'n v. FCC*, 253 F.3d 732, 734 (D.C. Cir. 2001); *see id.* at 736 (refusing to sever when doing so "would create a rule that the Commission did not consider" and which "would not have accomplished the Commission's two goals as it described them"). Here, FDA never separately evaluated any potential subset of its warnings so there is no reason to believe that a severed rule would achieve its goals.

inevitably suffer from the same constitutional problems. The Court should break this cycle by striking down both the Rule *and* the Act's graphic-warnings requirement. "If at first you don't succeed, try, try again" is not a phrase that should apply to First Amendment violations.

The Rule has yet more flaws. FDA violated the Administrative Procedure Act ("APA"), 5 U.S.C. § 500 *et seq.*, in multiple ways—most notably, by promulgating a Rule that the record evidence showed would not advance FDA's goal of educating the public about smoking risks, and instead would mislead and confuse consumers. FDA also violated the APA by conducting a cost-benefit analysis that expressly declined to quantify the Rule's benefits, by withholding necessary information from the public, by giving the public just fifteen days to comment on FDA's own qualitative studies (which further illustrated the Rule's defects), and by ignoring peer reviewers' fundamental criticisms. In addition, FDA lacked statutory authority to revise the textual warnings.

For each of these reasons, Plaintiffs are entitled to summary judgment, including a permanent injunction. In addition, to preserve the status quo while the Court is considering the motion for summary judgment, the Court should immediately enjoin the Rule pending resolution of the merits. If preliminary relief is not granted, Plaintiffs will suffer the irreparable harm of having their First Amendment rights violated. Moreover, based on the Court's reasoning in its May 8, 2020 Order, Plaintiffs would be irreparably harmed by being forced to spend millions of dollars and thousands of employee hours to comply with the Rule, expenditures which Plaintiffs would not be able to recover if the Rule were to be invalidated. Indeed, Plaintiffs are already suffering irreparable harm because they have been forced to take costly steps to prepare for the Rule's mandated label changes in order to achieve compliance by the deadline.

STATEMENT OF THE ISSUES

The Tobacco Control Act mandates that cigarette packages and advertising bear one of nine new textual warnings, that FDA "issue regulations that require color graphics depicting the negative

health consequences of smoking to accompany" those textual warnings, and that the graphic images and textual warnings take up fully 50% of cigarette packages and 20% of cigarette advertising. 15 U.S.C. § 1333. On March 18, 2020, FDA issued the Rule. 85 Fed. Reg. 15,638. The dispositive issues presented are whether (1) the Rule and the Act's graphic-warnings requirements violate the First Amendment, (2) the Rule violates the APA, and (3) the Rule violates the Tobacco Control Act. An additional issue presented is whether Plaintiffs are entitled to a preliminary injunction.

STATEMENT OF THE CASE

For decades, textual warnings have appeared on all cigarette packages and advertising. Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (1965); Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200 (1984). At the same time, the government has systematically limited Plaintiffs' avenues for advertising cigarettes to adult consumers. *See, e.g.*, *id.* § 1335, 21 U.S.C. § 387a-1(a)(2); 21 C.F.R. §§ 1140.16, 1140.34. Even before the Rule, Plaintiffs' avenues of communication were limited principally to (1) cigarette packages and (2) advertising through retail points of sale, magazines, and direct, one-on-one communications with adult cigarette consumers who have agreed to receive them. The Rule severely burdens these remaining avenues of communication by commandeering Plaintiffs' packages and advertising to disseminate emotionally-charged anti-smoking messages. FDA's record provides no basis to conclude that the warnings will impact consumers' smoking behavior or meaningfully educate the public about smoking risks that they are not already well aware of.

A. The Tobacco Control Act Transforms Cigarette Warnings From Factual Disclosures Into Government-Mandated Anti-Smoking Advocacy.

In 2009, Congress enacted the Tobacco Control Act, Pub. L. No. 111-31, which transformed the current cigarette warnings into government-mandated anti-smoking advocacy. The Act requires that cigarette packages and advertising bear one of nine textual warnings. 15 U.S.C. § 1333(a)(1),

(b)(1).[3] The Act also directs FDA to "issue regulations that require color graphics depicting the negative health consequences of smoking to accompany" these warnings. *Id.* § 1333(d)[1]. Together, the textual warnings and color graphics must occupy the top 50% of the front and back of cigarette packages and the top 20% of cigarette advertising. *Id.* § 1333(a)(2), (b)(2).

The Act gives FDA a limited ability to adjust the textual warnings before they take effect: FDA may "adjust the type size, text and format of the label statements … so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area." *Id.* § 1333(d)[1]. After the warnings take effect, the Act allows FDA to "adjust the format, type size, color graphics, and text of any of the label requirements" if doing so "would promote greater public understanding of the risks associated with the use of tobacco products." *Id.* § 1333(d)[2].

B. FDA's First Graphic-Warnings Rule Compelled Plaintiffs To Disseminate Grotesque Anti-Smoking Images In Violation Of The First Amendment.

In 2011, FDA issued a rule implementing the Act's graphic-warnings requirement. *Required Warnings for Cigarette Packages and Advertisements*, 76 Fed. Reg. 36,629 (June 22, 2011) ("2011 Rule"). The 2011 Rule required that all cigarette packages and advertising bear one of nine disturbing images, including a body on an autopsy table, diseased body parts, and a wailing baby. FDA said that the 2011 Rule would "reduc[e] the number of Americans … who use cigarettes" by making consumers "depressed, discouraged, and afraid" to buy them. 76 Fed. Reg. at 36,629, 36,638 (quotation marks omitted). And FDA freely admitted that, after the 2011 Rule took effect, "every single pack of

[3] The statutory textual warnings are: (1) "WARNING: Cigarettes are addictive."; (2) "WARNING: Tobacco smoke can harm your children."; (3) "WARNING: Cigarettes cause fatal lung disease."; (4) "WARNING: Cigarettes cause cancer."; (5) "WARNING: Cigarettes cause strokes and heart disease."; (6) "WARNING: Smoking during pregnancy can harm your baby."; (7) "WARNING: Smoking can kill you."; (8) WARNING: Tobacco smoke causes fatal lung disease in nonsmokers."; and (9) "WARNING: Quitting smoking now greatly reduces serious risks to your health." Plaintiffs do not challenge the dissemination of the purely factual information contained in these textual warnings. Plaintiffs instead challenge the Act's requirement that the warnings occupy the top 50% of the front and back of cigarette packages and the top 20% of cigarette advertising, the Act's requirement that FDA issue a graphic-warnings rule, and the Rule itself.

cigarettes in the country" will in effect become a "'mini billboard' for the government's anti-smoking message." *R.J. Reynolds*, 696 F.3d at 1212 (quoting FDA, *Tobacco Strategy Announcement* (Nov. 10, 2010)).

In 2012, the U.S. District Court for the District of Columbia held that the 2011 Rule violated the First Amendment, reasoning that the 2011 Rule's compelled warnings were "neither factual nor accurate," and were not narrowly tailored to achieve a sufficiently compelling government interest. *R.J. Reynolds Tobacco Co. v. FDA*, 845 F. Supp. 2d 266, 273 (D.D.C. 2012). Later that year, the D.C. Circuit affirmed the district court's holding. *R.J. Reynolds*, 696 F.3d 1205. The court began by analyzing whether the 2011 Rule was subject to the standard of scrutiny set forth in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), under which "purely factual and uncontroversial disclosures are permissible if they are reasonably related to the State's interest in preventing deception of consumers, provided the requirements are not unjustified or unduly burdensome." *R.J. Reynolds*, 696 F.3d at 1212 (quotation marks omitted). The court held that *Zauderer* did not apply to the 2011 Rule for three reasons. *First*, the warnings were not "reasonably related to the State's interest in preventing deception of consumers." The court explained that the Tobacco Control Act already prohibited misleading statements on cigarette packages and advertising, and neither Congress nor FDA had found that the warnings were necessary to prevent consumer deception. *Id.* at 1214–15.[4] *Second*, the warnings were not "purely factual." As "FDA tacitly admit[ted]," the warnings were "primarily intended to evoke an emotional response, or, at most, shock the viewer into retaining the information in the text warning." *Id.* at 1216. Because the warnings were "unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting," they were not purely factual. *Id.* at 1217.

[4] The D.C. Circuit later held that, under *Zauderer*, a compelled disclosure need not be reasonably related to preventing consumer deception. *Am. Meat Inst.*, 760 F.3d at 31. But that ruling conflicts with this Circuit's decision in *Hersh v. United States ex rel. Mukasey*, 553 F.3d 743, 764–68 (5th Cir. 2008), which applied strict scrutiny, rather than *Zauderer*, to a compelled commercial disclosure that was not reasonably related to preventing consumer deception. *See also infra* pp. 20–22.

Third, the warnings were not "uncontroversial"; rather, "many of the images chosen by FDA could be misinterpreted by consumers." *Id.* at 1216.

The court then held that the 2011 Rule failed to satisfy the standard set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980). The court first held that "FDA ha[d] not provided a shred of evidence … showing that the graphic warnings will 'directly advance' its interest in reducing the number of Americans who smoke." *Id.* at 1219. The court then held that FDA's asserted interest in "effectively communicating health information regarding the negative effects of cigarettes" was "purely informational" and "not an independent interest capable of sustaining the Rule." *Id.* at 1221. The court therefore vacated the rule and remanded to FDA.

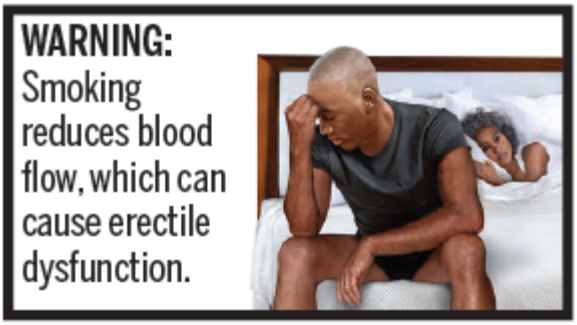
C. FDA's Second Graphic-Warnings Rule Likewise Compels Plaintiffs To Disseminate Grotesque Anti-Smoking Images.

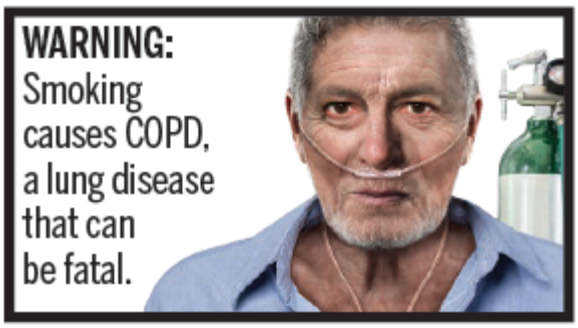
On August 16, 2019, FDA issued a proposed rule again implementing the Act's graphic-warnings requirement. *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 84 Fed. Reg. 42,754 (Aug. 16, 2019) ("Proposed Rule"). During the 60-day comment period, FDA received extensive comments. *See, e.g.*, Comment Letter of RAI Services Co., Docket No. FDA-2019-N-3065 (Oct. 11, 2019) ("Reynolds Comments"). On March 18, 2020—more than seven years after the D.C. Circuit vacated the 2011 Rule—FDA issued the final Rule at issue here. 85 Fed. Reg. at 15,638–710. The effective date of the Rule was originally set to June 18, 2021, *id.* at 15,638; in its May 8 Order, this Court postponed the effective date to October 16, 2021.

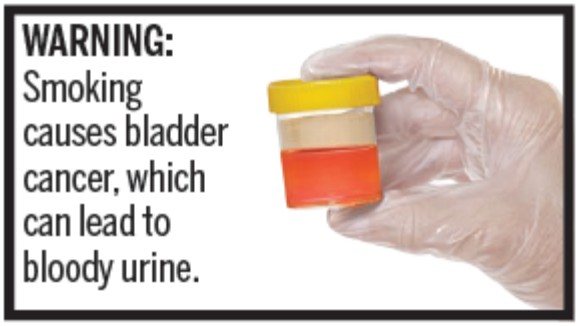
In the current Rule, FDA abandoned its previously asserted interest of "reducing the number of Americans … who use cigarettes." 76 Fed. Reg. at 36,629. Indeed, FDA repeatedly emphasized that "increased smoking cessation and decreased initiation are not the purpose of this rule." 85 Fed. Reg. at 15,650; *see id.* at 15,660; 15,665. Instead, FDA said that the Rule would "promote greater public understanding of the negative health consequences of cigarette smoking." *Id.* at 15,638. In particular, FDA said that it wanted to advance this interest by focusing on "less-known health consequences of

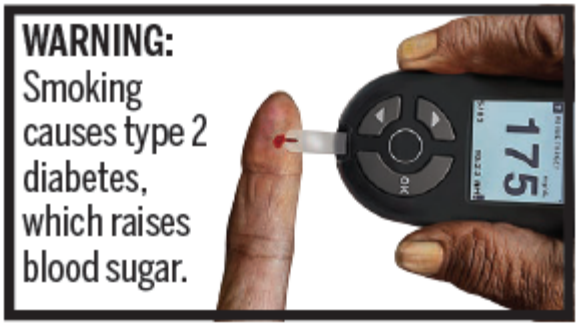
smoking." *Id.* at 15,640.

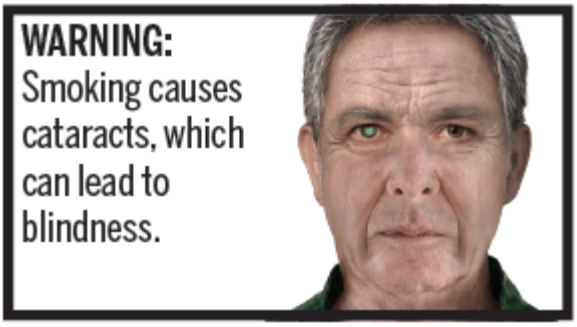
The Rule deleted seven of the Act's textual warnings, added nine of FDA's own creation, and adopted eleven graphic images. *Id.* at 15,685, 15,708–09. Together, the following textual warnings and graphic images must occupy the top 50% of the front and back of cigarette packages and the top 20% of cigarette advertisements. *Id.* at 15,709.

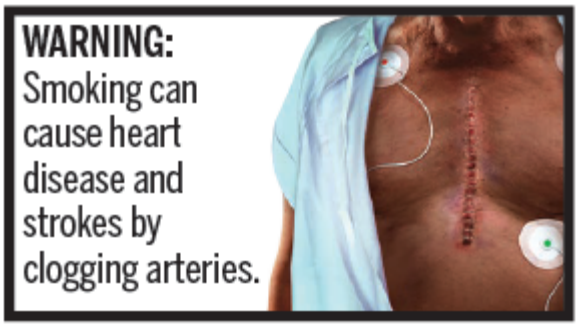












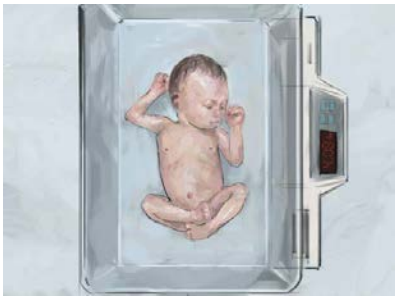
D. FDA Selected Warnings That Would Frighten, Shock, And Disgust Consumers.

FDA's new Rule suffers from the same core defects as the first one. In the 2011 Rule, FDA conceded that it designed the warnings to make consumers "depressed, discouraged, and afraid" to buy cigarettes. 76 Fed. Reg. at 36,638 (quotation marks omitted). The D.C. Circuit thus held that those warnings were "unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting." *R.J. Reynolds*, 696 F.3d at 1217. FDA has been less transparent this time, but the evidence demonstrates that it took the same approach here.

The images themselves betray FDA's motives. FDA selected a horrific array of images, including a woman with a baseball-sized neck tumor, a cup filled with bloody urine, a pair of diseased feet with several amputated toes, a pair of diseased lungs post-autopsy, and a wailing baby on a scale. Common sense dictates that these images will frighten, shock, and disgust viewers. *See infra* p. 23–25.

Despite the images' obvious emotional impact, and despite the D.C. Circuit's invalidation of the initial set of images as "unabashed attempts to evoke emotion," FDA avoided asking any study participant how the new warnings made them feel. FDA conducted "16 qualitative focus groups" and

a "quantitative consumer research study" for the textual warnings, 84 Fed. Reg. at 42,767, and "53 in[-]depth individual interviews," "20 qualitative focus groups," and another "consumer research study" regarding the graphic images and warnings, *id.* at 42,770–71. Yet FDA did not ask any questions about whether the warnings triggered feelings such as fright, shock, or disgust. Reynolds Comments, Exh. C, Stmt. of J. Klick ¶ 5.80 ("Klick Report"); *see also* 85 Fed. Reg. at 15,668 ("an assessment of emotional responses or behavioral study outcomes is not aligned with the final rule"). Although FDA did not ask, many study participants *volunteered* that the warnings made them feel this way. Participants reported that the images were "grotesque," "gruesome," "disgusting," "heartbreaking," "startling," "powerfully disturbing," "scary," and "terrifying." Siegel+Gale, *FDA Graphic Health Warning Image Concept Testing* at 37, 62, 97, 126, 130, 138, 142 (June 2016) ("Second Qualitative Study Report"). Participants also said the images "send[] me into despair," "really creep me out," "really just disgust[] me," had "shock value," and depicted "my worst nightmare." *Id.* at 24, 97, 130, 138, 142. Instead of changing course in the face of these reactions, FDA doubled down. For example, study participants said that an early version of the "Diseased Feet" image was "startling," "powerfully disturbing," and "disgusts me." *Id.* at 126, 130. And study participants said that an early version of the "Crying Baby" image was "heartbreaking," "emotional," and "would really creep me out." *Id.* at 97. FDA responded by making the "Diseased Feet" image *more* grotesque, and by making the baby appear *more* distraught.



FDA also repeatedly accepted recommendations to make the images more emotional. For example, FDA accepted recommendations to "[m]aintain the look of dismay (e.g., sadness in the eyes)" for the "Sick Child" image, to "[m]ake the blood on the gloves more discernible" for the "Diseased Lungs" images, to "[z]oom in a bit so the blood is more discernible" for the "Diabetes" image, to "[m]ake it clear that the man's emotion is shame" for the "Erectile Dysfunction" image, and to "[m]aintain the look of sadness/despair" for the "Neck Tumor" image. *Id.* at 158–59, 161, 165–66.

FDA initially tried to bury the evidence of the warnings' emotional impact. When FDA issued the Proposed Rule, it refused to release the qualitative study reports, which included participants' reactions to the warnings and highlighted FDA's drive to make the warnings even more evocative. After several commenters criticized FDA for failing to release the reports, FDA relented—*after* the comment period had closed. FDA then gave the public fifteen days to comment on these reports, which spanned nearly 600 pages. *See infra* p. 53–55.

E. FDA's Own Analysis Shows That The Selected Warnings Would Mislead Consumers And Convey Inaccurate Information About Smoking Risks.

FDA's new Rule also suffers from a second fundamental defect: The selected graphic warnings convey a host of factually inaccurate and misleading messages to consumers about smoking health risks. Public comments in the administrative record demonstrate that all of the Rule's warnings misleadingly exaggerate the risks of smoking. *See infra* pp. 26–27. And FDA's own qualitative studies reinforced the point. The responses of the study participants further showed that the graphic warnings convey misleading, confusing, or inaccurate messages. *See infra* p. 28.

At a minimum, participants' reactions to FDA's draft graphic warnings raised serious questions about the clarity and accuracy of the messages the warnings conveyed. *See infra* pp. 28–29. But instead of probing these issues, FDA withheld the qualitative study reports for months, and declined to undertake similar studies of the *final* graphic warnings to establish whether those warnings solely conveyed straightforward, accurate, non-misleading information. Instead, FDA sought to brush aside the inconvenient implications of the qualitative studies because they were "not nationally representative, and do not yield data that can be generalized," 85 Fed. Reg. at 15,666—even though the "quantitative studies" on which FDA *did* rely suffered from similar limitations. *See infra* p. 15.

F. FDA's Own Analysis Shows That The Rule Will Not Meaningfully Affect The Public's Knowledge Of Smoking Risks.

1. Before issuing the Proposed Rule, FDA commissioned two quantitative studies. The first was designed to determine whether the FDA-created textual warnings would promote greater public understanding of smoking risks. 84 Fed. Reg. at 42,767. The study split participants into seventeen groups—one of which viewed the Tobacco Control Act's nine textual warnings, and sixteen of which viewed eight of the Act's warnings and one of the FDA-created warnings. RTI Int'l, *Experimental Study on Warning Statements for Cigarette Graphic Health Warnings: Study 1 Report* at 2-1(16) (Apr. 2018) ("First Quantitative Study Report").[5] The study then asked participants "a series of questions assessing beliefs about the negative health consequences of smoking contained in the warning statements." *Id.* at 2-3(18).

The second study was designed to determine whether the graphic warnings (including the textual warnings and the graphic images) would increase understanding of smoking risks. 84 Fed. Reg. at 42,771. The study split participants into seventeen groups—one of which saw a cigarette package and advertisement with one of the current textual warnings, and sixteen of which saw a package and

[5] This report and the report pertaining to FDA's second quantitative study were not consecutively paginated. This Motion provides the labeled page number and the PDF page number (in parentheses).

advertisement with one of the new graphic warnings. RTI Int'l, *Experimental Study of Cigarette Warnings: Study 2 Report* at 2-1(13) (May 2019) ("Second Quantitative Study Report"). The study (1) tested participants' beliefs about smoking risks, (2) showed them the warnings, (3) re-tested their beliefs after one day, and (4) re-tested their beliefs after fourteen days. *Id.* at 2-3–2-4(15–16).

2. Both studies had "significant short comings" that make them "unreliable." Klick Report ¶ 8.4. In particular, both studies used a "convenience sample" rather than a nationally representative sample. *See* First Quantitative Study Report at 4-4(85); Second Quantitative Study Report at 4-2(118). The U.S. Office of Management and Budget ("OMB") thus concluded that the study findings "may not generalize to the broader U.S. population." OMB, *Notice of Office of Management and Budget Action, Experimental Study on Warning Statements for Cigarette Graphic Health Warnings*, Ref. No. 201708-0910-011 (Jan. 29, 2018), https://tinyurl.com/ybwk7ptv ("OMB Notice"); *see also infra* pp. 15, 49–50.

These studies also were not peer reviewed before FDA issued the Proposed Rule, which led to criticism that they "were not credible." 85 Fed. Reg. at 15,661. FDA responded that its studies had been peer reviewed *subsequent* to the Proposed Rule, and it claimed that the reviewers were largely positive, providing only minor suggestions "to improve the clarity of the study reports." *Id.*

Contrary to FDA's characterization, the peer reviewers raised serious, substantive concerns about FDA's studies. *See* Final Summary Report: External Letter Peer Review of FDA's Quantitative Consumer Research on Cigarette Health Warnings Required by the Family Smoking Prevention and Tobacco Control Act (Nov. 19, 2019), https://tinyurl.com/yx5ee66g ("Peer Review Report").[6]

First, reviewers noted that both quantitative studies lacked an adequate theoretical framework to support the concepts for which they purported to be testing. *See id.* at 7 ("looks a little like *post-hoc*

[6] Relevant excerpts of the Peer Review Report and other documents are attached to this Motion. *See* Local Rules CV-7(b), CV-56(d). The parties will also submit a joint appendix pursuant to the Court's May 8, 2020 Order. For the Court's convenience, Plaintiffs previously submitted the Proposed Rule, Final Rule, Plaintiffs' comments, and Peer Review Report as exhibits to the Complaint.

rationalization"); *id.* at 23 ("neither based in empirical evidence nor theory"); *id.* at 12, 19, 43, 57, 60 (similar). Reviewers were concerned that FDA did not use "standard" measures, and failed to demonstrate the validity of its novel measures. *Id.* at 12, 15, 19, 20; *see also id.* at 9, 27, 43. Reviewers were particularly critical of the "primary outcomes" FDA used to measure understanding—self-reported learning and new information—and noted the lack of "prior research showing the validity and meaningfulness" of those measures to assess understanding. *Id.* at 18; *see id.* at 25 ("I am concerned the measures deployed . . . are not convincing measures of the underlying constructs that the research is targeting."). Reviewers also found FDA's decision to differentiate between "primary" and "secondary" outcomes in the first study to be "arbitrary." *Id.* at 14; *see id.* at 40.

Second, reviewers criticized FDA for failing to use representative samples (and instead using convenience samples with significant asymmetries). Reviewers noted that using a convenience sample "brings with it a host of potential biases and limits to generalizability versus employing a representative sample." *Id.* at 40; *see id.* at 38 ("key limitation"); *id.* at 44 ("significant weakness"); *id.* at 45 ("quite serious" limitation); *id.* at 48, 28, 34.

Third, reviewers raised a host of other analytical concerns. For example, reviewers were concerned that FDA's testing method primed study participants, skewed the results, and tested memory rather than understanding. *See id.* at 15 (test of participants' "memory and test taking skills" rather than "understanding"); *id.* at 32–33 (FDA asking about beliefs "at baseline distorts the way people process the information"); *id.* at 60 ("priming effect"). Reviewers also expressed concerns about the conclusions FDA drew from the data because the revised warnings were ranked "lower" on "factualness" than the Surgeon General's warnings. *Id.* at 23; *see id.* at 33 ("[f]acticity" results are a "problem"). A reviewer also criticized FDA's failure to include the believability criterion in the second study, "because these results undermined the legitimacy and utility of the warnings." *Id.* at 33.

FDA made minimal effort to address these fundamental flaws, refusing to make substantive

revisions. For example, in response to a suggestion that additional measures be used, FDA replied that "Study 1 is complete, and we are unable to include new measures in this study." FDA, Response to External Peer Review of Quantitative Consumer Research on Cigarette Health Warnings Required by the Family Smoking Prevention and Tobacco Control Act, at 8 (Feb. 4, 2020), https://tinyurl.com/yx5ee66g. FDA likewise did not add measures to its second study and defended its use of novel measures. *Id.* at 16. And FDA did not resolve the problems with the studies' samples, or address any other structural defect identified by the reviewers. It merely added "clarifying details" and stated that none of its updates "changes the results, findings, or conclusions." 85 Fed. Reg. 15,661.

3. Even taken at face value, however, these studies demonstrate that the Rule will not have a material impact on the public's understanding of smoking risks. *First*, these studies show that the public already knows about many of those risks. Specifically, the first quantitative study showed that the "[Act's] warning statements were new information to relatively few participants," First Quantitative Study Report at 5(6), and that participants did not consider eight of the nine FDA-created textual warnings in the final Rule (the "diabetes," "amputation," "cataracts," "bladder cancer," "erectile dysfunction," "head and neck cancer," "heart disease," and "fetal growth" warnings) to be more "informative" than the Act's warnings. *Id.* at 3-11(72).

Second, the studies performed dismally when it came to altering participants' beliefs about smoking risks, which is the best measurement of whether the warnings would promote greater public understanding of those risks. The first study showed that, when compared to the Act's textual warnings, seven of the nine FDA-created textual warnings in the final Rule (the "cataracts," "bladder cancer," "erectile dysfunction," "head and neck cancer," "heart disease," "fetal growth," and "COPD" warnings) did not have a statistically significant effect on the participants' beliefs after adjustments for multiple comparisons. First Quantitative Study Report at (6)7, 2-2(17), 316–3-17(76–78). And the second quantitative study fared little better. That study showed that five of the Rule's eleven warnings

(the "harm your children," "erectile dysfunction," "heart disease," "fetal growth," and "COPD" warnings) did not have a statistically significant effect on participants' beliefs. *See* Second Quantitative Study Report at 3-15–3-17(111–13). In addition, five more warnings had a small effect on the participants' knowledge after one day, but a much smaller effect after fourteen days. *See id.* at at 3-10–3-11(106–07), 3-14–3-15(110–11) (showing that the alleged increase in knowledge had dropped by 66% for "diabetes," 50% for "head and neck cancer," 50% for "cataracts," 40% for "bladder cancer," and 34% for "amputation").[7] In other words, out of eleven warnings, five had no effect on participants' knowledge, and five more had only a small effect that quickly began to dissipate. This indicates that FDA's purported "health beliefs assessment" was not actually testing participants' understanding or acceptance of the information, and was at most capturing their ability to recall it.

G. The Rule Will Harm Plaintiffs.

Plaintiffs R.J. Reynolds Tobacco Company, Santa Fe Natural Tobacco Company, Inc., and ITG Brands, LLC manufacture, sell, and advertise cigarettes. Decl. of Lamar W. Huckabee ¶¶ 1–3, 5, 15 ("Huckabee Decl."); Decl. of Kim Reed ¶¶ 1–2, 5, 15 ("Reed Decl."). Plaintiff Liggett Group LLC manufactures cigarettes and, through an affiliate, sells and advertises them. Decl. of Francis G. Wall ¶¶ 3, 24–25 ("Wall Decl."). Plaintiffs Neocom, Inc., Rangila Enterprises Inc., Rangila LLC, Sahil Ismail, Inc., and Is Like You Inc. (the "Retailer Plaintiffs") operate convenience stores in Texas (including three in Tyler) that sell cigarettes and display cigarette packages and advertising. Decl. of Nooralam Erkin ¶¶ 2, 4 ("Erkin Decl."); Decl. of Suleman Ismail ¶¶ 2–5, 7 ("Ismail Decl.").

As detailed below and in the attached declarations, the Rule and the Tobacco Control Act's graphic-warnings requirement compel Reynolds, Santa Fe, ITG Brands, and Liggett (the

[7] The percentages result from comparing the increase in mean health beliefs from Session 1 to Session 2 to the increase in mean health beliefs from Session 1 to Session 3. For example, for diabetes, the study found a .74 increase in knowledge between Session 1 and Session 2, and a .25 increase between Session 1 and Session 3. *Id.* at 3-11(107), 3-15(111). A reduction from .74 to .25 is a 66% reduction.

"Manufacturer Plaintiffs") to place emotionally charged, misleading graphic warnings on their cigarette packages and advertising. 15 U.S.C. § 1333; 85 Fed. Reg. 15,638. As further described below, the Rule and Act's requirement that tobacco manufacturers engage in this compelled speech, with which they vehemently disagree, will cause all of the Plaintiffs First Amendment injury and economic injury. Huckabee Decl. ¶¶ 8–17; Reed Decl. ¶¶ 7–17; Wall Decl. ¶¶ 4–30; Erkin Decl. ¶¶ 5–10; Ismail Decl. ¶¶ 8–13.

STANDARD OF REVIEW

Plaintiffs' challenges to the Rule and the Act's graphic-warnings requirement are pure legal questions. *See Girling Health Care, Inc. v. Shalala*, 85 F.3d 211, 215 (5th Cir. 1996). Thus, the only questions are whether Plaintiffs are "entitled to judgment as a matter of law," Fed. R. Civ. P. 56(a), and whether they are entitled to a preliminary injunction under Federal Rule of Civil Procedure 65.

ARGUMENT

I. PLAINTIFFS ARE ENTITLED TO SUMMARY JUDGMENT ON THEIR CLAIMS.

A. The Rule Violates The First Amendment.

The First Amendment protects "both the right to speak freely and the right to refrain from speaking at all." *Janus v. Am. Fed'n of State, Cty., & Mun. Employees, Council 31*, 138 S. Ct. 2448, 2463 (2018) (quotation marks omitted). As Justice Jackson famously explained: "If there is any fixed star in our constitutional constellation, it is that no official, high or petty, can prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or *force citizens to confess by word or act their faith therein*." *W. Va. Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943) (emphasis added). Compelled speech "violates that cardinal constitutional command." *Janus*, 138 S. Ct. at 2463.

These principles apply "not only to expressions of value, opinion, or endorsement, but equally to statements of fact the speaker would rather avoid." *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Boston*, 515 U.S. 557, 573 (1995). And they apply to "ordinary people" and "business corporations"

alike. *Id.* at 574. "For corporations as for individuals, the choice to speak includes within it the choice of what not to say." *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n*, 475 U.S. 1, 16 (1986) (plurality op.).

To overcome the right not to speak, the government generally must satisfy strict scrutiny, which requires the speech compulsion to be "narrowly tailored to serve compelling state interests." *Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2226–27 (2015); *see also Wooley v. Maynard*, 430 U.S. 705, 714–15 (1977). This demanding test reflects the high cost of compelled speech. When the government forces persons to speak, they are "coerced into betraying their convictions." *Janus*, 138 S. Ct. at 2464. "Forcing free and independent individuals to endorse ideas they find objectionable is always demeaning, and for this reason, one of [the Supreme Court's] landmark free speech cases said that a law commanding 'involuntary affirmation' of objected-to beliefs would require 'even more immediate and urgent grounds' than a law demanding silence." *Id.* (quoting *Barnette*, 319 U.S. at 633). As such, compelled speech is, like other forms of viewpoint discrimination, "presumptively unconstitutional." *Rosenberger v. Rector & Visitors of Univ. of Va.*, 515 U.S. 819, 830 (1995); *see also Iancu v. Brunetti*, 139 S. Ct. 2294, 2302 (2019) (noting that a "finding of viewpoint bias ended the matter").

The Supreme Court has established a narrow exception to the "fundamental rule … that a speaker has the autonomy to choose the content of his own message." *Hurley*, 515 U.S. at 573–74.[8] Specifically, the government may compel commercial speakers to disclose "purely factual and uncontroversial information about the terms under which [their] services will be available," so long as the disclosure is "reasonably related to the State's interest in preventing deception of consumers" and is not "unjustified or unduly burdensome." *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985). But *Zauderer* does not apply here, and the Rule would not satisfy that standard even if it did.

[8] Plaintiffs contend that strict scrutiny should govern *all* regulations of commercial-speech, including compelled disclosures. *See Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 255–56 (2010) (Thomas, J., concurring in part and concurring in the judgment). Although Plaintiffs expressly preserve that issue for later review, this brief applies controlling precedent.

1. The *Zauderer* standard of review does not apply.

(a) The Rule's warnings are not reasonably related to "consumer deception."

At the threshold, the *Zauderer* standard cannot apply here because the warnings are not "reasonably related to the State's interest in preventing deception of consumers." *Zauderer*, 471 U.S. at 451. In *Zauderer*, the Court affirmed that *misleading* commercial speech does not merit similar protection as lawful, non-misleading commercial speech. The Court also explained that, when the government seeks to combat misleading speech, it has options short of banning the speech. In particular, it may consider "disclosure requirements" as a "less restrictive alternativ[e] to actual suppression of speech," so long as the compelled disclosure is "reasonably related to the State's interest in preventing deception of consumers." *Id.* at 651 & n.14. Applying that standard, the Court upheld Ohio's requirement that an attorney provide additional "purely factual and uncontroversial information" necessary to cure otherwise deceptive commercial advertising. *Id.* at 651.

In the decades since, the Supreme Court has held the use of the *Zauderer* standard appropriate only when commercial speech is potentially deceptive or misleading and a compelled disclosure would fix that problem. Indeed, the Court has confirmed that "the essential features of the rule at issue in *Zauderer*" were that the "required disclosures [were] intended to combat the problem of inherently misleading commercial advertisements" using "only an accurate statement." *Milavetz*, 559 U.S. at 250. And the Court has repeatedly declined to apply *Zauderer* outside the context of correcting deceptive speech. For example, in *Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136, 146 (1994), the Court invalidated a required disclaimer because it was not "an appropriately tailored check against deception or confusion" under *Zauderer*. *See also United States v. United Foods, Inc.*, 533 U.S. 405, 416 (2001). The Supreme Court has never allowed the government to compel speech, unless necessary to

remedy an otherwise false or misleading commercial message, without satisfying heightened scrutiny.[9]

The *Zauderer* standard is thus limited to the context in which it makes sense—when a court must assess the lawfulness of a compelled disclosure necessary to make a commercial advertisement nonmisleading. In that context, there is likelier to be a close fit between the regulation and the government's consumer-protection interest, and concomitantly lower constitutional concern with the impact of the regulation on the potentially misleading commercial speech. Consistent with this view, the Fifth Circuit has recognized that a less-exacting *Zauderer* review applies only to regulations aimed at preventing consumer deception. For example, in *Allstate Insurance Co. v. Abbott*, 495 F.3d 151 (5th Cir. 2007), the Fifth Circuit invalidated a law requiring insurers who promote their favored automobile repair shops to also promote other repair shops. *See id.* at 157, 164–68. The court held that, because the advertisement the insurer would use without the mandated disclosure carried only a "minimal" "potential for customer confusion," heightened scrutiny, rather than *Zauderer*, applied. *Id.* at 166; *see also Hersh*, 553 F.3d at 764–68 (applying strict scrutiny, rather than *Zauderer*, to a compelled commercial disclosure that was not reasonably related to preventing consumer deception); *Test Masters Educ. Servs., Inc. v. Robin Singh Educ. Servs., Inc.*, 799 F.3d 437, 453 (5th Cir. 2015) (explaining that Supreme Court "created [the *Zauderer*] standard to gauge" required disclosures "directed at deceptive or misleading commercial speech"); *accord Dwyer v. Cappell*, 762 F.3d 275, 282–83 (3d Cir. 2014); *Cent. Ill. Light Co. v. Citizens Util. Bd.*, 827 F.2d 1169, 1173 (7th Cir. 1987); Reynolds Comments at 10.

Here, there is no plausible case that the graphic warnings are necessary to prevent consumer deception. Federal law already prohibits Plaintiffs from making false or misleading claims through cigarette packages and advertising. *See* 21 U.S.C. §§ 331(a), 387c(a)(1), (7), 387k; *see also R.J. Reynolds*,

[9] Multiple Justices of the Supreme Court have noted that "*Zauderer* carries no authority for a mandate unrelated to the interest in avoiding misleading or incomplete commercial messages." *Glickman v. Wileman Bros. & Elliott, Inc.*, 521 U.S. 457, 491 (1997) (Souter, J., joined by Rehnquist, C.J., and Scalia and Thomas, JJ., dissenting); *see also Milavetz*, 559 U.S. at 257 (Thomas, J., concurring).

696 F.3d at 1214–15. In addition, FDA acknowledges that its goal is to "promote greater public understanding," not prevent consumer deception. *See* 85 Fed. Reg. at 15,668. And while FDA halfheartedly contends that the warnings are "intended in part to correct consumer misperceptions," this claim is inapposite for two reasons. *First*, the operative question, as the Fifth Circuit explained in *Test Masters*, is whether the commercial speech at issue is deceptive or misleading, not whether consumers are imperfectly informed more generally. 799 F.3d at 453. *Second*, even if past consumer deception were relevant, FDA makes no attempt to show that any previous misrepresentations by tobacco companies continue to mislead consumers today despite more than five decades of federal health warnings. Moreover, the Rule governs not just tobacco manufacturers but also tobacco retailers (including several of the Plaintiffs). *See, e.g.,* 85 Fed. Reg. at 15,690; 15 U.S.C. § 1333(b)(1). And there is no suggestion that the Retailer Plaintiffs *ever* engaged in any deceptive speech relating to tobacco. Accordingly, compelling their speech is improper (and cannot be justified under *Zauderer*).

Because the Rule is not intended to, and does not in fact, compel disclosures necessary to correct Plaintiffs' purportedly misleading speech, *Zauderer* does not apply here.

(b) The Rule's warnings are not "purely factual."

More generally, the narrow *Zauderer* exception applies only to compelled disclosures of "purely factual" information. *Zauderer*, 471 U.S. at 651. But the Rule's warnings are not "purely factual" either; they are "intended to evoke an emotional response," to "shock the viewer," and to convey an ideological message that consumers should not smoke. *R.J. Reynolds*, 696 F.3d at 1216–17; *see also Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006). Thus, *Zauderer* does not apply.

As an initial matter, the Rule's required dissemination of purportedly photorealistic images excludes the warnings from *Zauderer* review. The *Zauderer* standard applies only to those compelled disclosures that convey "factually straightforward, evenhanded, and readily understood" information. *Am. Meat Inst.*, 760 F.3d at 34 (Kavanaugh, J., concurring). Meeting that requirement is difficult enough

with respect to textual warnings about perceived health risks. *See, e.g.*, *Am. Beverage Ass'n v. City & Cty. of S.F.*, 871 F.3d 884, 895 (9th Cir. 2017) (finding that textual warning that drinking sugar-sweetened drinks "contributes to obesity, diabetes, and tooth decay" inaccurately "conveys the message that [these] beverages contribute to these health conditions regardless of the quantity consumed or other lifestyle choices"), *aff'd on reh'g*, 916 F.3d 749 (2019) (agreeing that warning did not meet *Zauderer* standard, on different grounds). For photorealistic images, meeting that requirement is virtually impossible, as they are inherently susceptible to multiple, subjective interpretations and lack precise meaning. *See R.J. Reynolds*, 696 F.3d at 1216 (recognizing images will give rise to subjective interpretations and misinterpretations). At a minimum, it will be very difficult for the government to prove that, in fact, the public consistently understands a given image as conveying a specific, purely factual proposition. The government did not even attempt to create such a record here.

Moreover, the government's inclusion of the images *in addition to* the (purportedly factual) textual warning statements demonstrates that the images are necessarily serving a purpose other than communicating purely factual information. The most natural inference is that the images are being used not to *convey facts*, but to scare consumers. And a review of the images FDA has chosen to attach to the words vividly demonstrates that they are intended to elicit fear, not to convey purely factual information. For example, the warnings include images of a sick child wearing a breathing mask; bloody, diseased lungs from a dead person; diseased feet with several toes missing; a specimen cup filled with bloody urine; a woman with a massive neck tumor; and a tiny, crying baby on a scale.

A litany of news organizations recognized that these warnings disgust viewers and convey an ideological, anti-smoking message. For example, the Washington Post called the warnings "scary" and "unsettling," and noted that the D.C. Circuit previously struck down "similarly graphic labels"; the New York Times called the warnings "disturbing"; Psychiatry Advisor called them "gruesome"; and the Huffington Post called the warnings "ghastly" and "grisly." Reynolds Comments at 5.

In addition, a survey contained in the administrative record found that 85.9% of respondents believe that the warnings are "trying to make people feel afraid," 85.4% believe that the warnings are "trying to shock people," and 74.5% believe that the warnings conveyed the message that people "should not smoke" cigarettes. Reynolds Comments, Exh. E, S. Iyengar, *NERA Survey: Consumer Perceptions of Cigarette Warning Labels*, at ¶ 29, 31 & App'x 3 ("Iyengar Report").

FDA's tactics are no closer to mere informational disclosures than any of the "shock and awe" advocacy used in numerous ideological debates, such as when animal-rights activists display photographs of mutilated animals. Although such photographs illustrate the actual treatment of animals, no one would contend that they are "purely factual." To the contrary, such images are designed to "shock" others into agreeing with the non-factual message that the targeted practice is socially unacceptable and should be stopped. Similarly, no one would contend that the government could mandate the following as "purely factual" warnings:

Moreover, the qualitative study reports demonstrate that FDA tried to make the warnings as emotional as possible. Although FDA refused to ask the study participants how the warnings made them feel, those participants repeatedly described the images as "grotesque," "gruesome," "disgusting," "heartbreaking," "startling," "powerfully disturbing," "scary," "terrifying," "send[] me into despair," "would really creep me out," "really just disgust[] me," had "shock value," depicted "my

worst nightmare," and, in one case, as "the perfect image to show somebody you don't want to smoke." Second Qualitative Study Report at 24, 37, 62, 97, 126, 130, 138, 142; *see also* Appendix to Motion (cataloging similar consumer reactions). But FDA ignored those responses, and instead made the warnings *more* frightening, *more* shocking, and *more* disgusting. *See supra* pp. 10–12. And to top it all off, FDA tried to hide those damning reports from the public. *See supra* p. 12.

The Rule also requires that the warnings occupy the top 50% of the front and back of cigarette packages and the top 20% of cigarette advertising. 85 Fed. Reg. at 15,709. These requirements likewise indicate that the warnings are not intended to convey factual information. On the contrary, the combination of the size and location of the warnings, the use of both text *and* images, and the shocking nature of the graphics is designed to overwhelm, and thereby mute, Plaintiffs' own speech and shout the government's view about how people should live their lives.

In sum, FDA's graphic warnings are not the sort of "purely factual" information to which the *Zauderer* standard applies.

(c) The Rule's warnings are not "uncontroversial."

Zauderer prohibits even "purely factual" speech requirements if they are "controversial." *Zauderer*, 471 U.S. at 651. A disclosure is controversial when its factual accuracy is disputed. *See Am. Beverage*, 916 F.3d at 766 (Christen, J., concurring in part and concurring in the judgment); *Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 966-67 (9th Cir. 2009), *aff'd sub nom.*, *Brown v. Entm't Merchants Ass'n*, 564 U.S. 786 (2011). But even a factually accurate disclosure can be controversial in at least two situations. *First*, although strictly true, the forced speech nevertheless is intended to stir controversy rather than convey information. *Entm't Software*, 469 F.3d at 652. Here, for the reasons noted above, the graphic images are not intended to uncontroversially convey the information purportedly conveyed by the text, and are instead more akin to a picture of a mutilated animal on a meat package. The images are instead intended to "skew public debate" and "to stigmatize"

consumers—which makes them "hardly … non-ideological." *See Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 530 (D.C. Cir. 2015) (panel reh'g) (internal quotation marks omitted).

Second, compelled speech is controversial if the facts conveyed are exaggerated or otherwise could be misleading or misinterpreted. *See R.J. Reynolds*, 696 F.3d at 1216 (holding that FDA's first set of graphic warnings were controversial because they were "subject to misinterpretation by consumers"); *Entm't Software*, 469 F.3d at 652 (holding that a disclosure was "controversial" because the speaker might reasonably disagree with the message).

FDA's graphic warnings are controversial in that sense too, because they are misleading. *See R.J. Reynolds*, 696 F.3d at 1216 (noting that "many of the images chosen by FDA could be misinterpreted by consumers," for example by causing them to believe that a relatively rare procedure is in fact "a common consequence of smoking"). All of the Rule's warnings exaggerate smoking risks:

- The "Sick Child" image exaggerates the effects of secondhand smoke in two ways. *First*, it depicts a "worst case scenario": "a child hospitalized due to an asthma attack caused by … tobacco smoke." Reynolds Comments, Exh. G, Decl. of L. Brooks ¶ 4 ("Brooks Decl."). But children are rarely hospitalized for that reason. *Id.* ¶¶ 7–8. *Second*, the image's depiction of a breathing mask is "exaggerating" because it is "uncommon for a child with an asthma attack to require oxygen." *Id.* ¶ 5.

- The "Diseased Non-Smoker's Lungs" image also exaggerates the effects of secondhand smoke. *First*, "the lungs do not look like a non-smoker's lungs." Reynolds Comments, Exh. I, Decl. of M. Farber ¶ 4 ("Farber Decl."). To the contrary, the image depicts an "amount of black pigmentation" that "would likely result from many years of heavy direct smoking" and would be "very unusual … in a non-smoker." *Id.* ¶ 5. *Second*, it would be "unusual" for a non-smoker to have three cancerous lesions of the size depicted. *Id.* ¶ 6.

- The "Diseased Feet" image exaggerates the effects of smoking because it depicts a condition that could affect, at most, one in 1,000 smokers. Reynolds Comments, Exh. K, Decl. of Robert Wagmeister, MD ¶ 4 ("Wagmeister Decl.").

- The "Cataracts" image exaggerates the effects of smoking in two ways. *First*, the image is "not a reasonable depiction of persons with cataracts in the US, because in the US the cataract would have been treated surgically long before it got to this stage." Exh. H, Decl. of Jonathan M. Davidorf at 3 ("Davidorf Decl."). *Second*, the warning emphasizes a condition—blindness—that occurs in only a small minority of cases (0.48%) of cataracts. Comment Letter of Altria Client Services at 61, Docket No. FDA-2019-N-3065 (Oct. 15, 2019) ("Altria Comments").

- The "Neck Tumor" image exaggerates the effects of smoking by suggesting that "a cancerous mass of that size could arise quickly enough that a reasonable person would not have had an opportunity to seek treatment before this point." Reynolds Comments, Exh. J, Decl. of Kim R. Jones, MD ¶ 5 ("Jones Decl.").

- The "Open Heart Surgery" image misleadingly suggests that open heart surgery is the most common method of treating coronary artery disease. Reynolds Comments at 8.

- The "Crying Baby" image exaggerates the effects of smoking by depicting a newborn baby weighing four pounds. According to the U.S. Surgeon General, babies at the low end of normal birth weight who are born to smoking women would still weigh more than five pounds. *Id.* at 8.

- The "Bloody Urine" image is misleading. FDA itself cited "literature in which the association between bladder cancer and consistent smoking of up to ten cigarettes per day was not statistically significant." Comment Letter of ITG Brands at 12, Docket No. FDA-2019-N-3065 (Oct. 15, 2019) (citing 84 Fed. Reg. at 42,774) ("ITG Comments").

- The "Erectile Dysfunction" image fails to "convey either the absolute or relative risk of erectile dysfunction associated with smoking," and misleadingly suggests that this outcome is commonplace for smokers. *Id.* at 15. In support of this image, "the Agency cite[d] a study which found that the correlation coefficient between erectile dysfunction and smoking "after adjusting for age . . . was attenuated, -0.09 ($p < 0.02$)."' *Id.* (citing 84 Fed. Reg. at 42,776).

- The "COPD Nasal Cannula" image misleadingly "depicts a 'worst case scenario,' without any discussion in the administrative record of the proportion of smokers developing COPD who will require long-term oxygen therapy (or home oxygen), much less the proportion of all smokers who will require home oxygen." *Id.* at 14.

- The "Finger Prick" image is "misleading in that it does not convey either the absolute or relative risk of diabetes as a result of smoking," and instead suggests that smoking will result in development of diabetes requiring the use of painful finger stick blood glucose monitoring. *Id.* at 16.

In light of these misleading exaggerations, it is unsurprising FDA did not design its qualitative studies to determine the accuracy of the messages conveyed to consumers. Instead, FDA focused on whether the warnings conveyed new information, grabbed participants' attention, or were believed or understood by participants. *See, e.g.,* RTI Int'l, *Qualitative Study on Cigarettes and Smoking: Knowledge, Beliefs, and Misperceptions*, at 6–7 (July 2015) ("First Qualitative Study Report"); Second Qualitative Study Report at 11-13; RTI Int'l, *Qualitative Study on Consumer Perceptions of Cigarettes Health Warning Images* at 3

(Apr. 2018) ("Third Qualitative Study Report"). This gap necessarily means that the record fails to demonstrate that FDA's warnings are "uncontroversial."

Although FDA did not design its studies to target this issue, its studies demonstrated that, far from the graphic warnings accurately informing the public about smoking health risks, consumers will take away a host of misleading and inaccurate messages from the Rule's images and text. For example:

- The near-final "Erectile Dysfunction" image depicts a man sitting on a bed, with a woman in the background. Some study participants thought this image was about a "strained relationship," infertility, or perhaps "[i]nsomnia/sleeplessness," or "stress/depression." Third Qualitative Study Report at 70, 72.

- Some study participants were confused by the near-final "Sick Child" image, stating "that it was unclear what was wrong with the child." *Id.* at 14.

- The draft warning statement that "Smoking Causes Diabetes" inaccurately conveyed to consumers that smoking is the sole or primary cause of diabetes, or invariably causes diabetes. First Qualitative Study Report at 45.

- The early versions of the "Sick Child," "Diseased Feet," "Cataracts," and "Open Heart Surgery" images scored "low" on "clarity of message," and the early versions of the "Neck Tumor," "Crying Baby," and "Finger Prick" images rated only "medium" on clarity of message or image. Second Qualitative Study Report at 13, 16, 20.

- According to FDA's First Qualitative Study Report, "[t]he most prevalent finding across groups and statements was the negative reaction to statements of the type 'X causes Y' (e.g. 'cigarettes cause,' 'smoking causes,' 'tobacco smoke causes,' or 'secondhand smoke causes' … [specific disease / health effect]). Participants referred to these statements as 'blanket,' 'absolute' or 'definitive' statements.."' First Qualitative Study Report at 52.

Indeed, the reactions of study participants confirm that *every* graphic warning will mislead, confuse, or shock consumers. *See* Appendix.[10] This record amply demonstrates that consumers will frequently—and in many cases overwhelmingly—take away messages from the draft graphic warnings that are contrary to fact, or at minimum factually controversial.

[10] *See* First Qualitative Study Report at 15, 17, 19, 22, 26–29, 43–46; Second Qualitative Study Report at 13, 20, 22, 24, 26, 33, 35, 37–40, 42, 61–63, 77–78, 81, 93, 97, 125–26, 128, 130, 143–45, 158–59, 161, 164–65; Third Qualitative Study Report at 14, 16, 21, 23, 30, 44–45, 59, 64, 67–68, 70, 72.

These results should have caused FDA to undertake further qualitative consumer panel studies of the *final* graphic warnings to establish whether those warnings solely conveyed indisputably accurate, non-misleading information to consumers. But FDA did not. Despite acknowledging that the warnings should depict diseases as they are "typically experienced," 84 Fed. Reg. at 42,770, FDA developed misleading warnings that exaggerate the effects of smoking—and make the images more frightening, shocking, and disgusting. Such advocacy is subject to strict scrutiny, not *Zauderer*.

2. In any event, the Rule fails to satisfy the *Zauderer* standard.

Even if the Court erroneously applies *Zauderer*, the Rule still violates the First Amendment because it is "unjustified" and "unduly burdensome." *Zauderer*, 471 U.S. at 651.

(a) The Rule is "unjustified" because the public already knows the risks of smoking.

A compelled disclosure is "unjustified" if it addresses a "purely hypothetical" problem, such as telling the public information it "already know[s]." *Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2377 (2018) ("*NIFLA*") (quotation marks omitted); *see also Ibanez*, 512 U.S. at 146. But that is the only type of problem, and the only type of information, FDA has identified here.

As an initial matter, FDA does not argue that the Rule is justified by an interest in reducing smoking (and indeed it repeatedly disclaims any such interest, 85 Fed. Reg. at 15,660, 15,650, 15,665). In the 2011 Rule, FDA argued that graphic warnings would "reduc[e] the number of Americans … who use cigarettes." 76 Fed. Reg. at 36,629. But FDA completely abandoned that argument in the current Rule. And for good reason: FDA previously determined that graphic warnings would reduce smoking by a mere 0.088%, a number that was statistically indistinguishable from zero. *Id.* at 36,775–76. Accordingly, the D.C. Circuit held that "FDA has not provided a shred of evidence … showing that the graphic warnings will 'directly advance' its interest in reducing the number of Americans who smoke." *R.J. Reynolds*, 696 F.3d at 1219. In addition, FDA's own Population Assessment of Tobacco and Health ("PATH") survey shows that educating people about the risks described in the Rule will

have "zero direct effect on smoking behavior." Klick Report ¶ 5.37.

This time, FDA argues that the Rule will "promote greater public understanding of the negative health consequences of cigarette smoking." 85 Fed. Reg. at 15,638. There are two problems with that alleged interest. *First*, as then-Judge Kavanaugh explained, the government does not have a substantial interest in simply "giving consumers information." *Am. Meat*, 760 F.3d at 31 (Kavanaugh, J., concurring in the judgment). "After all, that would be true of any and all disclosure requirements." *Id.* at 32. In other words, as the D.C. Circuit has recognized, the government's informational rationale can only be understood as a *means* of achieving an appropriate, tangible real-world effect. *R.J. Reynolds,* 696 F.3d at 1221; *see Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 73–74 (2d Cir. 1996); *Edenfield v. Fane*, 507 U.S. 761, 770–71 (1993). But here, the government identifies no such beneficial real-world effect, because there is none. For that reason, the government's "purely informational" interest is not "capable of sustaining the Rule." *R.J. Reynolds*, 696 F.3d at 1221.

Second, even assuming FDA could mandate irrelevant disclosures, mandating these graphic warnings will not advance any significant informational interest. The Supreme Court held in *NIFLA* that a compelled disclosure cannot remedy a harm by telling people things that they "already know," 138 S. Ct. at 2377, and the public "already know[s]" about the risks of smoking. For decades, cigarette packages and advertising have displayed warnings that inform the public about smoking risks. *See* Pub. L. No. 89-92, 79 Stat. 282 (1965); Pub. L. No. 98-474, 98 Stat. 2200 (1984). The public has also received such information from other sources, including the government, public-health entities, doctors, insurers, and schools. *See* Klick Report ¶¶ 5.6, 5.9, 5.10; Reynolds Comments, Exh. D, Report of Jan-Benedict Steenkamp § 3.2 ("Steenkamp Report"); Reynolds Comments at 13; *see also United States v. Philip Morris USA Inc.*, No. 99-CV-2496 (GK), 2016 WL 3951273, at *1 (D.D.C. Apr. 19, 2016) (requiring tobacco companies to make corrective statements). As a result, the public already knows that smoking is harmful. Indeed, FDA's own PATH survey shows that *99.5%* of individuals believe

that cigarette smoking is harmful to health, with 91% believing that it is "very or extremely harmful," 7% believing it is "somewhat harmful," and 1.5% believing it is "slightly harmful." Klick Report ¶ 5.20.

The public also knows about the major risks of smoking. For example, PATH data show that 94% of people believe that smoking cigarettes causes lung cancer, 94% believe that smoking causes lung disease, and 88% believe that smoking causes heart disease. Klick Report ¶¶ 5.41, 5.43, 5.48. Indeed, the public actually *overestimates* many of these risks. *Id.* ¶ 5.68–71. As one study demonstrated, smokers and non-smokers alike "substantially over-estimated the lung cancer rate of smokers, as well as the contribution of smoking to over-all mortality and expected losses in lifespan." *Id.* ¶ 5.71.

It would be difficult, if not impossible, to improve these numbers. Experts generally agree that, "[a]s a practical matter, getting to awareness levels above 80 or 90 percent is unrealistic." Klick Report ¶ 5.17. Indeed, the percentage of Americans who know that smoking is harmful to health is higher than the percentage of Americans who know that the Earth revolves around the sun (74%), or the percentage of young Americans who know where the United States is on a map (94%). Reynolds Comments at 14. Thus, the public universally understands the major risks of smoking.

FDA effectively concedes this point. FDA begins the Proposed Rule by describing major risks, such as lung cancer, COPD, heart disease, and stroke. 84 Fed. Reg. at 42,758. FDA then *contrasts* these major risks with "other health conditions" that are "less known to the public." *Id.*; *see also id.* at 42,756, 42,764. FDA likewise concedes that the public has an effectively universal awareness of the risks described in the Tobacco Control Act. For example, FDA admits that, in its first quantitative study, "relatively few participants reported that the content of the [Act's] statements was new information." *Id.* at 42,768. FDA likewise admits that "the public already has a high pre-existing level of knowledge of the specific health consequences described in the warnings tested in [four] studies, some of which included warning statements set forth by Congress in the Tobacco Control Act." *Id.* at 42,764. Because those four studies tested *all* of the Act's warnings, FDA has effectively conceded that the public

"already has a high pre-existing level of knowledge" of each of those risks. *See also id.* at 42,767 n.5.

FDA tries to sidestep this problem on the pretext that its messages address "less-known health consequences of smoking." *Id.* at 42,756–57. This is fundamentally flawed for two reasons. *First*, FDA's evidence shows that seven of the Rule's warnings describe *well-known* risks:

- **"Tobacco smoke can harm your children."** This warning comes from the Tobacco Control Act, 15 U.S.C. § 1333(a); FDA has thus conceded that this risk is well known. *See supra* pp. 31–32; *see also* First Qualitative Study Report at 33, 35 (stating that this warning was new information to only 2.6% of adults); Klick Report ¶ 5.59.

- **"Tobacco smoke causes fatal lung disease in nonsmokers."** This warning likewise comes from the Act, 15 U.S.C. § 1333(a), which means that it is well-known. *See supra* pp. 31–32. In addition, FDA's PATH data show that 83% of people believe that second-hand smoke causes lung disease in non-smokers. Klick Report ¶ 5.60.

- **"Smoking causes head and neck cancer."** The Proposed Rule relies on a 2018 article showing that people know smoking causes head and neck cancers, such as throat cancer (94.6%), oral cancer (87.3%), mouth cancer (93.5%), and esophagus cancer (82.1%). 84 Fed. Reg. at 42,761 (citing Dannielle E. Kelley et al., *Effective Message Elements for Disclosures About Chemicals in Cigarette Smoke*, 20 Nicotine & Tobacco Research 1047, 1051 (2018)); *see also* Klick Report ¶ 5.50.

- **"Smoking can cause heart disease and strokes by clogging arteries."** One of the Act's warnings says that "Cigarettes cause strokes and heart disease," 15 U.S.C. § 1333(a); thus, FDA has conceded that this information is well-known. *See supra* pp. 31–32; *see also* 84 Fed. Reg. at 42,758 (contrasting "heart disease" and "stroke" with "other health conditions" that are "less known to the public"). In addition, FDA's PATH data show that 88% of people believe that smoking causes heart disease, and 80% believe that smoking causes strokes. Klick Report ¶¶ 5.43, 5.45.

- **"Smoking during pregnancy stunts fetal growth."** PATH data show that 86% of people believe that smoking causes harm to fetuses. Klick Report ¶ 5.58. In addition, the Proposed Rule relies on a study showing that "[p]articipants knew about the risk of [low birth weight] and premature birth, supporting previous research on the topic." 84 Fed. Reg. at 42,761 (citing Denise M. Levis et al., *Women's Perspectives on Smoking and Pregnancy and Graphic Warning Labels*, 38(5) Am. J. of Health Behavior 755 (2014)); *see also* First Qualitative Study Report at 33.

- **"Smoking causes COPD, a lung disease that can be fatal."** In the Proposed Rule, FDA contrasts COPD with "less-known effects of smoking," thus conceding that this risk is well-known. 84 Fed. Reg. at 42,756. In addition, FDA's PATH data show that 94% of people believe that smoking causes lung disease. Klick Report ¶ 5.48; *see also* First Qualitative Study Report at 20.

Second, even if the public were not as aware of the less-known minor or unlikely negative health consequences covered by the *other* warnings (e.g., cataracts), the government lacks a substantial interest in requiring manufacturers and retailers to provide information about these less-known risks. The warnings about these risks serve no purpose because they will not affect smoking consumption (and FDA has not attempted to prove to the contrary), and generally will not even affect people's overall assessment of the risks of smoking. Klick Report ¶ 5.36. If citizens choose to smoke knowing that it can cause death from lung cancer and other diseases and harm their children, it is quite implausible that they would be deterred if they also knew it had some minor contributing effect on cataracts. As Dr. Jonathan Klick—a leading expert on the causal effects of health regulations and behavior—has explained, "for those who know smoking is deadly but are still inclined to smoke, risks like blindness and erectile dysfunction are likely not material." Klick Report ¶ 8.1. That is why no sensible regulator would require the disclosure that smoking stains one's teeth. FDA's effective concession that its warnings will not affect smoking levels empirically confirms this intuitively obvious point.

Moreover, FDA's *own* education campaign confirms this truism. FDA has spent hundreds of millions of dollars running public-education campaigns, such as *The Real Cost*, *Fresh Empire*, *This Free Life*, and *Every Try Counts* campaigns. Steenkamp Report § 3.2(C)–(F). Yet FDA has not cited *any* evidence showing that these campaigns addressed the risks described in the Rule. That omission is telling: if FDA truly believed that it had a substantial interest in educating consumers about cataracts or erectile dysfunction, then FDA would have said something about them in these campaigns. Similarly, FDA did not even try to quantify the benefits of giving consumers this information. Instead, FDA threw up its hands and said that "there is a high level of uncertainty around quantitative economic benefits." FDA, *Preliminary Regulatory Impact Analysis* at 2 (Aug. 2019) ("Cost-Benefit Analysis"); *see also* FDA, Final Regulatory Impact Analysis at 17, Docket No. FDA-2019-N-3065 (Mar. 2020) ("Final Regulatory Analysis") (similar). If FDA believed that giving people this information was

important, it should be able to say *something* about the measurable benefits of doing so.

(b) The Rule is also "unjustified" because it will not materially improve the public's understanding of the risks of smoking.

A compelled disclosure is also "unjustified" if it will not "remedy" any problem that exists. *NIFLA*, 138 S. Ct. at 2377; *see also Nat'l Ass'n of Mfrs.*, 800 F.3d at 525 (mandatory disclosure requirement violated *Zauderer* because the rationale for the requirement was "entirely unproven and rest[ed] on pure speculation"). The Rule inherently flunks this test because FDA does not even claim that it will "remedy" the only public health problem implicated here—smoking. *See* 85 Fed. Reg. at 15,650. Indeed, FDA does not even claim the Rule is intended to "increase perceptions of general harm of smoking" or to "educate the public about the absolute, relative, or dose-response risk" of smoking. *Id.* at 15,655, 15,669. Instead, FDA defines its goal remarkably narrowly: to promote "public understanding of the negative health consequences of smoking" only with respect to the "specific health consequences" depicted in the warnings. *Id.* at 15,655. But the government has no interest in increasing the public's knowledge on topics that are *immaterial* to their cigarette purchasing decisions, and therefore cannot possibly advance the public health goal of reducing smoking. And even if this were otherwise, the Rule is still facially invalid, because FDA has not provided any reason to believe that graphic warnings will serve even the abstract academic policy of increasing the public's understanding of smoking risks in question.

To begin with, there can never be a legitimate governmental interest in mandating *misleading* disclosures. *See Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 967 (9th Cir. 2009), *aff'd sub nom.*, 564 U.S. 786 (2011); *Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 539 (D.C. Cir. 2015) (Srinivasan, J., dissenting). Because the graphic warnings would mislead consumers about the less well known risks of smoking, they cannot be upheld under any level of First Amendment scrutiny. *See supra* pp. 26–28.

FDA's Rule also suffers from a second fundamental problem: the government cannot scare people into changing their smoking beliefs (or, for that matter, behavior). Dr. John Martin, a

behavioral-health psychologist with experience helping smokers quit, made this point to FDA during the comment period. As he explained, "[n]euroscience supports the [conclusion] that smokers have a strong tendency to avoid high-threat messages." Reynolds Comments, Exh. F, Report of J. Martin at 5 ("Martin Report"). Dr. Martin's clinical experience confirms that smokers are "already aware" of the risks of smoking, yet "cho[o]se to avoid thinking about them." *Id.* at 6. Likewise, Professor Jan-Benedict Steenkamp, an expert in marketing communications, explained to FDA that a "negative emotion like fear" can undermine a message's effectiveness. Steenkamp Report at 17. A high level of fear "produces inhibiting effects," which may cause the audience to "emotionally block the message by tuning out, perceiving it selectively, or denying its arguments outright." *Id.* Thus, "[r]esearch has shown that anti-smoking messages and graphic health warnings using high levels of fear were ineffective." *Id.*; *see also* Reynolds Comments at 18 (citing studies); Altria Comments at 14 (same).

FDA's own analysis confirms this point. FDA conducted two quantitative studies: one to test whether the textual warnings led to a statistically significant change in study participants' beliefs about smoking risks, and one to test whether the graphic warnings had that effect. Dismal results ensued. The first study showed that, when compared to the Tobacco Control Act's textual warnings, *seven* of the nine FDA-created warnings did not lead to a statistically significant increase in the participants' beliefs that smoking has the negative health consequences corresponding to that warning. First Quantitative Study Report at 3-16–3-17(77–78). And the second study showed that five of the Rule's eleven graphic warnings had *no* significant effect on the participants' beliefs about smoking risks, and five more had only a small effect that quickly started wearing off. *See supra* pp. 16–17.

FDA did not do any follow-up testing to determine why the warnings did such a poor job of changing study participants' beliefs about smoking. But FDA's qualitative and quantitative studies offer several possibilities. For starters, many of the warnings simply repeat information that the public already knows. FDA concedes that the public already knows about the risks described in the Act's

textual warnings. *See supra* pp. 31–32. Yet study participants thought that eight of the ten FDA-created textual warnings (the "diabetes," "amputation," "cataracts," "bladder cancer," "erectile dysfunction," "head and neck cancer," "heart disease," and "fetal growth" warnings) were no more "informative" than the Act's warnings. First Quantitative Study Report at 3-11(72). The government cannot educate the public simply by telling people things that they "already know." *NIFLA*, 138 S. Ct. at 2377.

Moreover, many of the FDA-created textual warnings were not believable. During FDA's first qualitative study, study participants repeatedly told FDA that they did not believe the textual warnings. Yet FDA consistently ignored that feedback:

- Participants had a "widespread negative reaction" to warnings that said smoking "causes" a disease, rather than "can cause," "may cause," or "increases the risk of." First Qualitative Study Report at 7, 52. This was the study's "most prevalent finding." *Id.* at 52; *see also id.* at 15, 17, 19, 26, 27, 31, 33, 34, 35, 36, 38, 45, 46. Yet the vast majority of the warnings continue to use the word "causes."

- Participants also "expressed a desire for more information about the relationship between the amount and duration of smoking … to the health effects of smoking." *Id.* at 7; *see also id.* at 38, 52. This was one of the study's "key findings." Yet the warnings do not include any such information.

- Participants often did not believe warnings about less-intuitive risks—like bladder cancer, diabetes, or erectile dysfunction—without more information about how smoking causes them. *See id.* at 23–24, 45, 53. FDA again ignored this advice.

FDA's first quantitative study confirmed that the FDA-created textual warnings were not believable. Participants thought that six of those warnings (the "diabetes," "amputation," "cataracts," "bladder cancer," "erectile dysfunction," and "head and neck cancer" warnings)—including *all* of the warnings that addressed less-intuitive risks—were less "believable" than the Act's warnings. First Quantitative Study Report at 3-9(70). FDA ignored this feedback, refused to make any meaningful changes, and even dropped the "believability" question from the second quantitative study. *See* Peer Review Report at 34 ("What happened to believability?").

FDA responded to these poor results by effectively writing off its own test. FDA explained

that people's "health beliefs" were "unlikely to change with a single brief exposure to the text-only statements—as was provided in this first quantitative consumer research study." 84 Fed. Reg. at 42,769. Instead of designing a longer-term study, however, FDA moved the goalposts by switching its focus to two different questions: (1) whether the warning was "new information" to participants, and (2) whether participants reported that they "learned something" from the warning. *See id.* at 42,768, 42,771. But these questions are wholly unreliable.

First, the "new information" and "learned something" questions say little—if anything—about whether the warnings will improve the public's understanding of smoking risks. As FDA explains, learning is a two-step process: "[T]o understand a message, individuals must first attend to the message (i.e., notice and be made aware of the message), and then they must process the information in the message (i.e., acquire knowledge of and learn that information)." 85 Fed. Reg. at 15,665–66. But FDA's chosen measures do not capture this learning process; indeed, FDA relied on only two criteria—new information and self-reported learning—both of which were criticized by reviewers as non-standard measures of questionable validity. *See* Peer Review Report at 14, 18, 28.

FDA contends that "new information" helps with the *first* step because "people are more likely to pay attention to information that is new." 84 Fed. Reg. at 42,769. But FDA does not explain how "new information" helps with the *second* step: whether people will "acquire knowledge of and learn that information." 85 Fed. Reg. at 15,656. And it is quite easy to see how a warning that contains "new information" might not lead to learning. For example, a warning might convey "new information" in a confusing way, so people cannot understand what it means. Or a warning might convey "new information" that is not credible, so people do not believe it. Or a warning might convey "new information" in an offensive way, so people refuse to heed it.

FDA's own studies provide a compelling example. FDA says that the "erectile dysfunction" warning conveys "new information." *See* Second Quantitative Study Report at 3-6(102). But FDA's

study also shows that this warning was not believable, and neither the textual warning nor the graphic warning led to a statistically significant increase in the number of participants who believed that smoking caused this problem. *See* First Quantitative Study Report at 3-10(71), 3-16(77); Second Quantitative Study Report at 3-15(111). Similarly, *none* of the final graphic warnings "reliably outperform[ed] the current Surgeon General's warnings" on the "perceived factualness" criteria. 85 Fed. Reg. at 15,659. Indeed, most "were perceived as factual statistically significantly less than the Surgeon General's warnings." *Id.* at 15,660. FDA eventually had to admit this fact when it corrected an earlier study report which misleadingly suggested to the contrary. *Compare* Revised Second Quantitative Study Report, at ES-4, *with* Second Quantitative Study Report at 4(5).

In the end, FDA's assertion that "new information" will promote greater public understanding is nothing more than "mere speculation," *R.J. Reynolds*, 696 F.3d at 1219.

Second, even if these questions were relevant, the evidence that FDA developed failed to demonstrate *meaningful* gains in consumers' knowledge of relevant health risks. FDA tested whether the graphic warnings scored better on the "new information" and "self-reported learning" metrics than the current textual warnings did. 84 Fed. Reg. at 42,772. But that is an exceedingly low bar. The current warnings cover diseases like lung cancer, heart disease, and emphysema (a type of COPD) that practically everyone already knows about. *See supra* pp. 31–32. And as FDA repeatedly points out, the current warnings "have not changed in more than 35 years" and smokers see them "over 5,100 times per year." 85 Fed. Reg. at 15,653. That a graphic warning conveyed more "new information" than a 35-year-old, universally understood warning is a small achievement indeed.

Third, FDA cannot show that its studies are reliable. As explained above, neither of the studies is nationally representative, which means that their findings "may not generalize to the broader U.S. population." OMB Notice; *see* 85 Fed. Reg. at 15,660. Moreover, the studies are self-contradictory. For example, the first quantitative study concluded that all of the FDA-created textual warnings

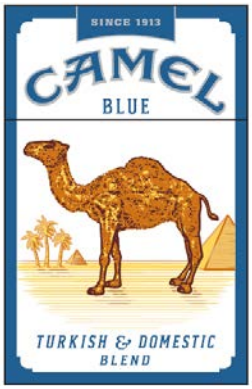
conveyed more "new information" than the Act's warnings. First Quantitative Study Report at 3-7–3-8(68–69). At the same time, however, eight of the ten FDA-created textual warnings were no more "informative" than the Act's warnings. *Id.* at 3-11(72). Both of those things cannot be true. Thus, the Court should give zero weight to the "new information" and "self-reported learning" questions.

(c) The Rule is "unduly burdensome."

The Rule also fails the *Zauderer* test because it is "unduly burdensome." 471 U.S. at 651. As the Supreme Court recently held, a compelled disclosure is "unduly burdensome" if it is "broader than reasonably necessary." *NIFLA*, 138 S. Ct. at 2377. In turn, a disclosure is broader than reasonably necessary if (among other things) the government cannot show that less-restrictive means are not sufficiently effective. *See, e.g., id.* at 2376 ("California argues that it has already tried an advertising campaign, and that many women who are eligible for publicly-funded healthcare have not enrolled. But California has identified no evidence to that effect."); *see also United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1143 (D.C. Cir. 2009) (per curiam).

Here, the Rule compels Plaintiffs to use the top 50% of the front *and* back of cigarette packages and the top 20% of cigarette advertising for gruesome warnings. These requirements impose onerous burdens on Plaintiffs in four primary ways.

First, the warnings drastically limit the physical space that manufacturers have to communicate. Reynolds Comments, Exh. L, Decl. of R. Claxton ¶ 16 ("Claxton Decl."). This requirement would force manufacturers to redesign the front and back of their cigarette packages, interfering with trademarks and trade dress. *Id.* ¶ 18. For example, the warnings will materially impair Reynolds's use of the "iconic Camel logo," which it has "used in various ways to identify the brand since 1913." *Id.*



Current pack front

Modified pack front

Manufacturers cannot fix this problem by simply shrinking their brand information to half its current size. Under federal law, cigarettes must be displayed several feet behind a sales counter. 21 C.F.R. § 1140.16(c); Claxton Decl. ¶ 24. As a result, substantially reducing the size of the brand message on those packages would make it very difficult to read. Indeed, if manufacturers had 50% less space on the front and back of cigarette packages for conveying messages, the words on those packages would quickly become illegible. *Id.* ¶ 25.

Second, the warnings themselves will make it harder for Plaintiffs to effectively convey information to consumers. FDA has adopted warnings that are designed to frighten, shock, and disgust consumers, and convey the government's anti-smoking message. *See supra* pp. 10–12. That will have one of two effects: either the images will pull consumers' attention away from Plaintiffs' message or they will repulse consumers and cause them to avoid looking at cigarette packages and advertising at all. Either way, the graphic images impose a heavy burden on Plaintiffs' speech. Claxton Decl. ¶ 15.

Third, the warnings exacerbate these problems by taking up the *top* portion of packages and advertising. The top portion is naturally the most prominent, so even under the best-case scenario, consumers will focus more on the graphic warnings than Plaintiffs' message. Claxton Decl. ¶ 16. But in many cases, the effect will be far worse. Many retail outlets arrange cigarette packages so only the top portion is visible, which would mean that consumers see *only* the graphic warnings. *Id.* ¶¶ 25, 26.

Current Retail Display

Modified Retail Display

Fourth, the combination of these factors—gruesome images that take up the top 50% of the front and back of cigarette packages—will make all cigarette packages look substantially the same. That makes it more difficult for manufacturers to "differentiate their brands from competitors' brands." Claxton Decl. ¶ 12; *see also id.* ¶ 4. This is burdensome to manufacturers who want to compete for market share against other brands.

All of these burdens are magnified because Plaintiffs have few remaining avenues for communicating with adult consumers.[11] Federal law prohibits Plaintiffs from advertising cigarettes on television and radio. 15 U.S.C. § 1335. Federal law also limits their ability to sponsor events, 21 U.S.C. § 387a-1(a)(2); 21 C.F.R. § 1140.34(c), sell or distribute promotional items, 21 U.S.C. § 387a-1(a)(2); 21 C.F.R. § 1140.34(a), and distribute free samples, 21 U.S.C. § 387a-1(a)(2)(G); 21 C.F.R.§ 1140.16(d). State law also imposes restrictions. *See* 15 U.S.C. § 1334(c) (federal law does not preempt various state restrictions); 21 U.S.C. § 387p (same). And a settlement between forty-six states and major cigarette manufacturers limits their ability to use billboard and transit advertising, paid product placement, event sponsorships, and advertising in sports stadiums. *See* Master Settlement Agreement § III(d), https://tinyurl.com/y6te8olv. Given that Plaintiffs have so "few avenues of communication" left with consumers, the Rule "place[s] a greater, not lesser, burden on [their] speech." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 564-65 (2001); *see also Linmark Assocs. v. Twp. of Willingboro*, 431 U.S. 85, 93 (1977).

[11] The Rule constitutes such a serious impingement on speech that it should be treated as a prohibition on speech and subjected to heightened scrutiny. *See Am. Meat*, 760 F.3d at 27 (a disclosure cannot be "so burdensome that it essentially operates as a restriction on constitutionally protected speech").

What is more, the government has plenty of less-restrictive ways to achieve its goals. Most obviously, the government could disseminate its anti-smoking message itself. It could, for example, increase funding for anti-smoking advertisements on television and radio and in other media. Steenkamp Report § 3.2(C)–(F). It could also issue additional statements in press conferences, press releases, and government reports, to urge consumers to quit smoking. Indeed, the Supreme Court recently held that a compelled disclosure did not survive intermediate scrutiny because, among other things, the state could have conveyed the information itself with such a "public-information campaign." *NIFLA*, 138 S. Ct. at 2376.

Moreover, a public-education campaign would work better than graphic warnings. A campaign would allow FDA to use different communication channels (e.g., television, radio, websites, and social media) that enable the speaker to convey more information than FDA can convey through graphic warnings. Steenkamp Report § 4.4. A campaign can also be changed more quickly than graphic warnings, which allows the speaker to convey current information. Klick Report ¶ 5.14. And a campaign can target particular groups by using different messages and different communication channels, rather than using a "one-size-fits-all message." Steenkamp Report § 3.1.

FDA is no stranger to public-education campaigns. Between 2009 and 2014, FDA spent more than $500 million on such campaigns. Reynolds Comments at 32. Since 2014, FDA has run multiple public-education campaigns, including *The Real Cost*, *Fresh Empire*, *This Free Life*, and *Every Try Counts*. FDA has touted these campaigns as "highly successful" and as "yielding tremendous results." *Id.* at 33 (quoting Norman E. Sharpless, *Press Announcement* (Aug. 20, 2019), https://tinyurl.com/y3kmouoa). Indeed, FDA alleged—just *four* days after issuing its Proposed Rule—that *The Real Cost* had "prevented up to 587,000 youth nationwide from initiating smoking between the campaign's launch in February 2014 and November 2016, half of whom might have gone on to become established smokers." *Id.* Given FDA's success with public-education campaigns in the past, the

government had an obligation to try one here.

The government also could make less-restrictive changes to the current warnings. For example, the government could change the warnings' text, location, size, or some combination of the three. But FDA never even "considered smaller or differently placed warnings." 85 Fed. Reg. at 15,650–51. FDA instead simply assumed bigger is better. If that reasoning prevails, however, nothing would prevent the government from commandeering 90% of the package without any weighing of the benefits and burdens. Moreover, the government has not shown that there is any need for graphic images in addition to textual warnings, which is an inherently redundant and unduly burdensome approach. In particular, FDA admitted it did not test revised text-only warnings. *Id.* at 15,650, 15,664. Even if the government is dead set on graphic warnings, it could have researched whether information can be effectively conveyed in a less burdensome manner, *e.g.*, by (1) requiring that the warnings occupy no more than 20% of cigarette packages and 10% of cigarette advertisements; (2) requiring the warnings to be placed solely on packages, or solely on advertisements, rather than on both; (3) requiring warnings on only the front *or* back of packages, not both; (3) allowing warnings to be placed on the bottom, rather than the top, of packages and advertising; (4) selecting graphics that convey purely factual information, rather than trying to inspire loathing for the product; or (5) some combination of these options. Whether or not such alternatives would ultimately satisfy the First Amendment, their existence—and FDA's complete failure to assess them—forecloses FDA from demonstrating that the Rule is the least-restrictive means of satisfying FDA's asserted interest.

In fact, FDA was on notice that these alternatives would have worked at least as well as its proposed graphic warnings. Textual warnings have worked before, helping to maintain the effectively universal knowledge about smoking risks like lung cancer, heart disease, and emphysema, *see supra* pp. 30–32, and FDA does not explain why they would not work again. In addition, a recent survey, which is part of the administrative record, compared FDA's warnings to several less-restrictive alternatives,

and found very few statistically significant differences regarding the amount of "new information" conveyed and respondents' beliefs about smoking risks after viewing the warnings. Iyengar Report ¶¶ 23–28. For example, for the "new information" question, there were no statistically significant differences between FDA's warnings and text-only warnings on the side of the pack. *Id.* ¶ 24. Likewise, for knowledge of smoking risks, there were no statistically significant differences between FDA's warnings and text-and-graphics warnings on the side of the pack. *Id.* ¶ 27. Other studies on less-restrictive alternatives have reached similar conclusions. Klick Report ¶ 7.12; Reynolds Comments at 31–32 (citing studies); Altria Comments at 40 (same).

New textual warnings might actually be *more* effective than graphic warnings because they do not rely on the type of fear-based appeals that cause some people to "reject[] the message as well as the messenger." Martin Report at 6. At the very least, however, the government "has failed to even explain why a smaller [warning] would not suffice." *Entm't Software*, 469 F.3d at 652. In 2018, Reynolds urged FDA to test several less-restrictive alternatives to see whether they would be as effective as graphic warnings. For example, Reynolds suggested that FDA "show one group of participants a package with the current [textual] warnings, show 16 groups a package with the new textual warnings, and show 16 more groups a package with the new textual warnings and graphic images." *See* Reynolds Comments at 32 (quoting RAIS Comments at 4, Docket No. FDA-2018-N-3552 (Nov. 16, 2018)). This type of study would have "allow[ed] FDA to determine how much the graphic images contribute, if at all, to FDA's stated goal" of conveying information to the public. *Id.* But FDA flatly refused to test this—or any other—alternative. *See* 85 Fed. Reg. at 15,650 (asserting that testing any alternative that is not contemplated by the TCA "would not have been an optimal use" of resources).

Courts have found that far smaller warnings are "unduly burdensome." For example, the Ninth Circuit recently invalidated a warning requirement that took up 20% of certain advertisements for sugar-sweetened beverages. *See Am. Beverage Ass'n*, 916 F.3d at 754. Although the court assumed

arguendo that the disclosure was factual and uncontroversial, the court held that the disclosure was "unduly burdensome" because smaller warnings would accomplish the government's goals. *See id.* at 757. Additionally, the Seventh Circuit concluded a four square-inch sticker—covering less than 10% of a package—"*literally* fail[ed] to be narrowly tailored." *Entm't Software*, 469 F.3d at 652 & n.13.

The warnings in this case are far larger: 50% rather than 20% or 10%. The warnings here also are far more distracting, given their use of gruesome images. And Plaintiffs have fewer remaining avenues for speech. *See Am. Beverage Ass'n*, 916 F.3d at 753–54 (explaining that the compelled disclosure about sugar-sweetened beverages did not apply to many types of communication). If the sugar-sweetened-beverage disclosure was unduly burdensome, then the graphic warnings are as well.

3. The *Central Hudson* standard is inapplicable, and the Rule would fail it in any event.

FDA has suggested that, if *Zauderer* does not apply, the Rule should be subject to the standard of review described in *Central Hudson*. 85 Fed. Reg. at 15,648. Under *Central Hudson*, courts must analyze four factors to determine whether "restrictions on commercial speech" violate the First Amendment: (1) whether the speech "concern[s] lawful activity" and is not "misleading"; (2) "whether the asserted governmental interest is substantial"; (3) "whether the regulation directly advances the governmental interest asserted"; and (4) "whether it is not more extensive than is necessary to serve that interest." 447 U.S. at 564, 566. By its own terms, however, *Central Hudson* applies to speech "restrictions," not compelled disclosures. *Id.* at 564; *see also Hersh*, 553 F.3d at 764–68 (applying strict scrutiny, rather than *Central Hudson*, to a compelled commercial disclosure to which *Zauderer* did not apply). Thus, if the government compels a commercial actor to express a message that is not subject to *Zauderer*, courts must apply strict scrutiny. *See, e.g.*, *Brown v. Entm't Merchants Ass'n*, 564 U.S. 786, 799 (2011); *Pac. Gas*, 475 U.S. at 17–18; *Hersh*, 553 F.3d at 764–68; *Entm't Software*, 469 F.3d at 652.

Moreover, even if the Court applied *Central Hudson*, the Rule would still violate the First Amendment. These factors align closely with the factors in *Zauderer*—indeed, as then-Judge

Kavanaugh has explained, "*Zauderer* is best read simply as an application of *Central Hudson*" to compelled commercial disclosures, "not a different test altogether." *Am. Meat*, 760 F.3d at 33 (Kavanaugh, J., concurring in the judgment). Thus, the Rule fails under *Central Hudson* for the same reasons it fails under *Zauderer*.

First, the Rule lacks a substantial interest. FDA argues that the Rule will "promote greater public understanding of the negative health consequences of cigarette smoking." 85 Fed. Reg. at 15,655. As noted above, since the government does not contend that this compelled speech will reduce smoking, the warnings serve no substantial interest, but only the purely academic interest of gratuitously providing consumers information that will not affect their purchasing decisions and, therefore, not affect public health. "For *Central Hudson* purposes . . . it is plainly not enough for the Government to say simply that it has a substantial interest in giving consumers information." *Am. Meat*, 760 F.3d at 31 (Kavanaugh, J., concurring in the judgment). Indeed, "that would be true of any and all disclosure requirements" and would "drain the *Central Hudson* test of any meaning in the context of compelled commercial disclosures." *Id.* Thus, such a "purely informational" interest is not "capable of sustaining the Rule." *R.J. Reynolds*, 696 F.3d at 1221; *see also supra* p. 30.

Second, the Rule will not advance the government's interest. Under this prong, FDA would need to show that the Rule "directly advances" its interest to a "material degree." *Edenfield*, 507 U.S. at 770–71. But, as explained above, FDA's own studies show that the warnings will not have an effect even on the academic goal of increasing the public's knowledge on topics immaterial to their level of smoking. *See supra* pp. 16–17. The Rule also fails to advance any goal of educating the public about smoking risks, because the compelled speech at issue will mislead the public about these risks. *See supra* pp. 26–28. Compelling a misleading or false warning cannot possibly advance any legitimate (much less substantial) government interest. *See, e.g., Video Software Dealers Ass'n*, 556 F.3d at 967.

Third, the Rule is "more extensive than is necessary to serve [the government's] interest." *Cent.*

Hudson, 447 U.S. at 566. Under this prong, "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371 (2002). But the government had numerous alternatives that would have been just as effective—if not more—than the graphic warnings. *See supra* pp. 42–44.

4. The Rule is subject to, and fails, strict scrutiny.

Because the Rule fails both *Zauderer* and *Central Hudson*, it necessarily fails the more-difficult standard of strict scrutiny. Under that standard, FDA has the burden of proving that the Rule substantially advances "a compelling interest and is narrowly tailored to achieve that interest." *Reed*, 135 S. Ct. at 2231. That is a demanding standard, and speech regulations "rarely" survive it. *Bernal v. Fainter*, 467 U.S. 216, 219 n.6 (1984).

The Rule is no exception. As explained above, the Rule lacks even a substantial interest, much less a compelling one. *See supra* pp. 29–39; *see also Brown*, 564 U.S. at 803 n.9 ("the government does not have a compelling interest in each marginal percentage point by which its goals are advanced"). Even if a compelling interest existed, the Rule is not narrowly tailored to it. *See supra* pp. 39–45.

In short, if the government wants to disseminate its anti-smoking viewpoint, it must find other ways to do so. It may be more convenient for the government to conscript cigarette manufacturers' property to convey its message. But the Constitution is a bulwark against such coercion. *Palmer v. Thompson*, 403 U.S. 217, 226 (1971); *see also Sorrell*, 564 U.S. at 552, 578–79. Because the Rule does not use the least-restrictive means of advancing a compelling interest, it cannot satisfy strict scrutiny.

B. The Tobacco Control Act's Graphic-Warnings Requirement Also Violates The First Amendment.

FDA has now issued two graphic-warnings rules, and both violated the First Amendment. That is no surprise—the Tobacco Control Act *mandates* that FDA issue warnings with a facially unconstitutional purpose. The Act directs FDA to "issue regulations that require color graphics depicting the negative health consequences of smoking." 15 U.S.C. § 1333(d)[1]. And the Act requires

that the warnings occupy the top 50% of the front and back of cigarette packages and the top 20% of cigarette advertising. *Id.* § 1333(a)(2), (b)(2). Those requirements are designed to shock viewers; as Sen. Enzi explained, "We should want kids who are thinking about taking up this deadly habit to have a bit of a shock just by looking at the package." 155 Cong. Rec. S6497, S6499 (daily ed. June 11, 2009) (statement of Sen. Enzi); *see R.J. Reynolds Tobacco Co. v. FDA*, 823 F. Supp. 2d 36, 52 (D.D.C. 2011) (Congress failed to even "contemplate the First Amendment implications when formulating its statute"), *aff'd*, 696 F.3d 1205 (D.C. Cir. 2012).

FDA has previously acknowledged this point. The first time that FDA tried to implement the Act's graphic-warnings requirement, the Agency said that "risk information is most readily conveyed by warnings that elicit … strong emotional and cognitive reactions." 76 Fed. Reg. at 36,697. FDA thus selected images with the goal of making consumers "depressed, discouraged, and afraid" to buy cigarettes. 76 Fed. Reg. at 36,638 (quotation marks omitted). FDA also said that, after the rule took effect, "every single pack of cigarettes in our country will in effect become a mini-billboard" for the government's anti-smoking message. *R.J. Reynolds*, 696 F.3d at 1212 (quoting FDA, *Tobacco Strategy Announcement* (Nov. 10, 2010)). FDA may wish to distance itself from those statements now, but they represent the Agency's best interpretation of the Act. And that interpretation is correct: The Act's required graphic warnings exist to frighten, shock, and disturb consumers, and to persuade them not to smoke. Thus, the Act's requirement violates the First Amendment for the same reasons the Rule does, and this Court should invalidate both. *See United States v. Salerno*, 481 U.S. 739, 745 (1987).

C. The Rule Violates The Administrative Procedure Act.

1. FDA acted arbitrarily and capriciously.

The APA directs courts to set aside agency action that is "arbitrary [and] capricious." 5 U.S.C. § 706(2)(A). "[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a "rational connection between the facts found and the choice made." *Motor Vehicle*

Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (quotation marks omitted); *accord Sw. Elec. Power Co. v. EPA*, 920 F.3d 999, 1013 (5th Cir. 2019). This mandate gives rise to at least four subsidiary requirements, each of which FDA violated.

First, an agency acts arbitrarily and capriciously when it "offer[s] an explanation for its decision that runs counter to the evidence before the agency." *State Farm*, 463 U.S. at 43; *see Sw. Elec. Power*, 920 F.3d at 1019. The APA also requires that agency action be supported by substantial evidence. *See R.J. Reynolds Tobacco Co.*, 696 F.3d at 1218; *Safe Extensions, Inc. v. FAA*, 509 F.3d 593, 604 (D.C. Cir. 2007).

Here, the Rule fails under these standards for all of the same reasons it fails First Amendment review. Most significantly, the Rule lacks *any* evidence demonstrating that the warnings will further FDA's only asserted interest: "promot[ing] greater public understanding" of smoking risks. 84 Fed. Reg. at 42,755. To show that the warnings will promote public understanding of smoking risks, FDA puts its hope in its two quantitative studies. (Although FDA cites other studies, all of them involved different warnings and overwhelmingly discussed their effects on non-U.S. populations.)

Yet these two studies are deeply flawed. The studies' participants were "recruited from an Internet panel" and then "screened for inclusion into the study." FDA, *Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study on Warning Statements for Cigarette Graphic Health Warnings*, 82 Fed. Reg. 43,764 (Sept. 19, 2017). As OMB later explained, however, this recruitment method is subject to bias because "[p]anelists are recruited into the online panel using convenience sampling methods, and thus do not have a known probability of selection." OMB Notice. In addition, OMB said that "[r]ecruitment of the study sample from the online panel is also subject to bias resulting from potential differences between survey responders … and non-responders … in characteristics that may be associated with key study outcomes." *Id.*

Due to these problems, OMB granted the first quantitative study only limited approval and noted that, "[d]ue to the study design, convenience sampling methodology, and methods of analyses—

significant limitations exist with regard to the generalizability of results from this study." *Id.* OMB explained that FDA's findings "may not generalize to the broader U.S. population." *Id.* The second quantitative study suffered from the same problems. *See* Second Quantitative Study Report at 4-2(118). These are "significant short-comings" that make FDA's studies "unreliable." Klick Report ¶ 8.4.

Even taken at face value, these studies do not support FDA's Rule—they undermine it. These studies show that at least seven of the nine FDA-created textual warnings, and at least ten of the eleven graphic warnings, did not have a meaningful impact on people's health beliefs. *See supra* pp. 16–17, 35. FDA has not given a rational explanation for why it ignored these findings.

Second, "when an agency decides to rely on a cost-benefit analysis as part of its rulemaking, a serious flaw undermining that analysis can render the rule unreasonable." *Idaho Conservation League v. Wheeler*, 930 F.3d 494, 507 (D.C. Cir. 2019) (quotation marks omitted); *see also Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012). Here, FDA's cost-benefit "analysis" includes a fatal flaw: a complete failure to quantify the Rule's benefits. *Cf. Sw. Elec. Power*, 920 F.3d at 1019 (rejecting agency's defense that "it lacked data to evaluate the performance of other technologies"). In fact, FDA expressly disclaimed any attempt to quantify benefits. It said that "there is a high level of uncertainty around quantitative economic benefits" and thus chose to "describe them qualitatively." Cost-Benefit Analysis at 2. Thus, FDA could not "compare benefits and costs directly." *Id.* at 8.

Instead of attempting to quantify the Rule's benefits, FDA relied on a "break-even calculation." It estimated the Rule would cost about $1.6 billion, 84 Fed. Reg. at 42,756; 85 Fed. Reg. at 15,698, and then concluded that the Rule would be beneficial on net if the value of the warning on each cigarette package was "about $0.01." Cost-Benefit Analysis at 37–38; *see* Final Regulatory Analysis at 8. But FDA provided *no reason* to believe that the informational benefit is worth $0.01 or more per pack. Thus, FDA relied on mere speculation. *See* Reynolds Comments at 39–41.

Third, a rule is "arbitrary and capricious if the agency" ignores an alternative regulatory

approach that is "neither frivolous nor out of bounds." *Chamber of Commerce v. SEC,* 412 F.3d 133, 144-45 (D.C. Cir. 2005); *see also Sw. Elec. Power*, 920 F.3d at 1017–18, 1021–22; *Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795, 817 (D.C. Cir. 1983). FDA has failed to consider such regulatory approaches here, including by refusing to evaluate several less-restrictive alternatives proposed by Reynolds. *See supra* pp. 42–44. Instead, FDA considered only three alternative approaches and, even as to those alternatives, provided no rational explanation as to why it had not adopted them. Cost-Benefit Analysis at 43–54. For example, FDA considered requiring only nine warnings and found that doing so would be less costly than requiring more warnings. *Id.* at 51–54. And FDA did not (and could not) demonstrate that the greater cost of the proposed rule is offset by any greater benefit. FDA's unexplained and irrational refusal to adopt the less-burdensome alternative violates the APA.

Fourth, a rule is arbitrary and capricious if the agency fails "'to respond meaningfully' to objections raised by a party." *PPL Wallingford Energy LLC v. FERC*, 419 F.3d 1194, 1198 (D.C. Cir. 2005) (citing *Canadian Ass'n of Petroleum Producers v. FERC*, 254 F.3d 289, 299 (D.C. Cir. 2001)); *see also Cigar Ass'n of Am. v. FDA*, No. 1:16-CV-01460 (APM), 2020 WL 532392, at *13 (D.D.C. Feb. 3, 2020). FDA failed this test here. Most prominently, its only response to the criticism that it ignored the results of its own qualitative studies was that those studies "d[id] not yield data that can be generalized." 85 Fed. Reg. at 15,666–67. But FDA nevertheless "used" those studies "to inform further research and development," *id.* at 15,667. Accordingly, it was incumbent on FDA to address *the manner* in which it used the studies—for example, why it chose to "ma[k]e the images *more* gruesome" after learning the proposed warnings "would evoke negative emotions and thereby convey an ideological, anti-smoking message." *See* Comment Letter of RAI Services Co., Docket No. FDA-2019-N-3065, 5 (Nov. 25, 2019) ("Reynolds Supplemental Comments").

FDA repeatedly asserts that it developed the graphic warnings through a "science-based, iterative research process." *E.g.*, 84 Fed. Reg. at 42,755; 85 Fed. Reg. at 15,639. But the record belies

that assertion. On the contrary, FDA has been barreling toward a pre-ordained conclusion from the very beginning without any regard for the evidence, and can now offer only a "*post-hoc rationalization*" for that preordained outcome. *See* Peer Review Report at 7; *supra* pp. 14–15.

FDA's handling of the peer review report underscores this. Despite FDA's misleading suggestion that the peer review was largely positive, *see* 85 Fed. Reg. at 15,661, the reviewers identified fundamental weaknesses with FDA's studies, such as its unsupported reliance on the "self-reported learning" and new-information measures, *see e.g.*, Peer Review Report at 27–28, 33; *supra* pp. 14–15. Yet FDA did not address these weaknesses. Instead, it claimed that it performed "an in-depth review of the scientific literature" to select its novel measures—despite the peer reviewers' criticism on that very point—and claimed that making cosmetic, non-substantive changes to its studies was sufficient. *See* 85 Fed. Reg. at 15,661–62. And remarkably, FDA gave the public no opportunity to comment on any of this—even though it had implicitly recognized that peer review was *necessary*, by noting that its non-peer-reviewed studies did not represent an agency determination. *See* First Quantitative Study Report at 4-5; Second Quantitative Study Report at 1-2. That is quintessentially "arbitrary and capricious."

Fundamentally, FDA's view appears to be that no real evidence is necessary to impose these graphic warnings because, as a parent might say when feeding a sick child chicken soup, "it can't hurt." However, the APA (not to mention the Constitution) requires more than a chicken-soup rationale.

2. FDA failed to provide meaningful notice.

FDA also violated the APA by withholding important information from the public. The APA requires that agencies publish a general notice of proposed rulemaking that includes "a description of the subjects and issues involved" in the proposed rule. 5 U.S.C. § 553(b)(3). That notice must contain "sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully." *Nat'l Lifeline Ass'n v. FCC*, 921 F.3d 1102, 1115 (D.C. Cir. 2019); *see Phillips Petroleum*

Co. v. Johnson, 22 F.3d 616, 620 (5th Cir. 1994), *modified on other grounds* No. 93-1377, 1994 WL 484506 (Sept. 7, 1994). And that is particularly true regarding "technical studies and data that [the agency] has employed in reaching the decisions to propose particular rules." *N. Am.'s Bldg. Trades Unions v. OSHA*, 878 F.3d 271, 301 (D.C. Cir. 2017) (brackets and quotation marks omitted); *accord Kern Cty. Farm Bureau v. Allen*, 450 F.3d 1072, 1076 (9th Cir. 2006); *Texas v. EPA*, 389 F. Supp. 3d 497, 505 (S.D. Tex. 2019).

At every stage of the rulemaking, however, FDA hid important information from the public. This pattern began in June 2017, when Reynolds's outside counsel submitted a Freedom of Information Act request seeking documents regarding FDA's graphic-warnings research. Reynolds Comments, Exh. P, Letter from C. Ozier to FDA. FDA had already completed several of its qualitative studies, including the first qualitative study (completed in July 2015) and the second qualitative study (completed in June 2016). But FDA has refused to produce those documents—or any others.

The pattern continued with FDA's quantitative studies. For example, FDA issued a notice inviting comments on the second quantitative study, which was designed to determine whether the graphic warnings would increase understanding of smoking risks. 84 Fed. Reg. at 42,771. But the notice said little about the study's design. Indeed, the notice even failed to include the text and graphics that made up the warnings themselves—the very object of the study. FDA, *Experimental Study of Cigarette Warnings*, 83 Fed. Reg. 48,625 (Sept. 26, 2018).

Worst of all, FDA hid vital information from the public when it issued the Proposed Rule. FDA said that it conducted a "rigorous multistep process to develop, test, and refine" the proposed warnings. 84 Fed. Reg. at 42,771. That process involved three qualitative studies and two quantitative studies—all of which FDA relied on in the Proposed Rule. *See id.* at 42,765–72; *id.* at 42,777–78. But FDA did not release the underlying data for the qualitative studies, or even the study reports. Instead, FDA released only short descriptions of the studies in the Proposed Rule itself. 84 Fed. Reg. at 42,767, 42,771. FDA's failure to release these reports violates the "fairly obvious proposition that studies upon

which an agency relies in promulgating a rule must be made available during the rulemaking in order to afford interested persons meaningful notice and an opportunity for comment." *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 237 (D.C. Cir. 2008). In addition, FDA did not release the final data sets from the quantitative studies, which would have allowed Plaintiffs to examine the data quality and replicate FDA's statistical analyses. Commenters promptly requested this information, but FDA failed to produce it before the comment period closed. *See, e.g.*, Letter from A. Klingler, Docket No. FDA-2019-N-3065-0001 (Sept. 9, 2019); Letter from Altria Client Services, Docket No. FDA-2019-N-3065-0001 (Sept. 5, 2019). As described below, FDA eventually released the qualitative study reports, but to date, it has not released the underlying data for the qualitative or quantitative studies.

That means FDA has still not explained basic aspects of their studies or reasoning, such as why it chose to "highlight[] certain diseases over others" even when the depicted conditions are less serious or less common. Comment Letter of Altria Client Services at 4, Docket No. FDA-2019-N-3065 (Nov. 27, 2019) ("Altria Supplemental Comments"); *see also* Altria Comments at 29–32 (similar); Peer Review Report at 26 ("[T]his reviewer was a bit perplexed about the sources and topics that generated the new warnings."). Nor did FDA explain why it failed to test consumers' *actual* understanding of the potential health effects, as opposed to consumers' self-reported belief that they learned something new, or why it declined to consistently make the warnings less confusing by using conditional language (such as "can cause") rather than definitive language (like "causes"). *See* Reynolds Comments at 16; Reynolds Supplemental Comments at 7; 85 Fed. Reg. at 15,708–09.

3. FDA failed to provide a meaningful opportunity to comment.

FDA likewise violated the APA by failing to give the public sufficient time to comment on the qualitative study reports. After publishing a proposed rule, "the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." 5 U.S.C. § 553(c). That opportunity must be "meaningful," *Nat'l Lifeline Ass'n*, 921

F.3d at 1115, and it must include the chance to comment on the agency's evidence, *Owner-Operator Indep. Drivers Ass'n v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 201 (D.C. Cir. 2007); *see Phillips Petroleum*, 22 F.3d at 620. Indeed, the failure to "reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary" is a "serious procedural error." *Solite Corp. v. EPA*, 952 F.2d 473, 484 (D.C. Cir. 1991) (quotation marks omitted); *accord Kern*, 450 F.3d at 1076; *Texas*, 389 F. Supp. 3d at 505.

Here, FDA committed such an error through its treatment of the qualitative study reports. As noted, FDA failed to release those reports during the comment period, despite the Agency's reliance on them. *See supra* pp. 53–54. Nearly a month after the comment period closed, however, FDA finally placed them in the docket. *See Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Additional Materials; Reopening of the Comment Period*, 84 Fed. Reg. 60,966 (Nov. 12, 2019). FDA then gave the public a mere fifteen days to comment. *Id.* at 60,967–68. That too violated the APA.

As an initial matter, FDA failed to provide a coherent explanation about why it had failed to release these reports along with the Proposed Rule. FDA acknowledged that it "used [these studies] to inform further research," specifically by "test[ing] and refin[ing] image concepts and obtain[ing] feedback on which textual statements should be selected for further study." 84 Fed. Reg. at 60,967; *see* 85 Fed. Reg. at 15,667 (similar). At the same time, however, FDA said that it "did not originally include the qualitative study reports in the docket as FDA did not rely on these studies as part of the rulemaking." 84 Fed. Reg. at 60,967; *see* 85 Fed. Reg. 15,667 (similar).

In any event, courts have consistently held that a 15-day comment period is inadequate. *See, e.g.*, *Nat'l Lifeline Ass'n*, 921 F.3d at 1117 (two weeks inadequate); *Prometheus Radio Project v. FCC*, 652 F.3d 431, 453 (3d Cir. 2011) (28 days); *N.C. Growers' Ass'n v. UFW*, 702 F.3d 755, 770 (4th Cir. 2012) (10 days). Indeed, the Administrative Conference of the United States has said that sixty days is a "reasonable *minimum* time for comment." *Petry v. Block*, 737 F.2d 1193, 1201 (D.C. Cir. 1984). By giving

the public only fifteen days to comment, FDA deprived the public of the ability to comment meaningfully. During the initial comment period, Reynolds's experts analyzed whether the proposed warnings were misleading or provoked negative emotions. *See, e.g.*, Davidorf Decl. at 2–3; Jones Decl. ¶¶ 4–5; Farber Decl. ¶¶ 4–6; Wagmeister Decl. ¶ 4; Brooks Decl. ¶¶ 4–5, 7–8; Iyengar Report ¶¶ 29, 31 & App'x 3. These experts could have used the qualitative study reports to deepen that analysis, *see supra* pp. 10–13, but were unable to do so given the tight timeframe. In addition, if FDA had released these reports along with the Proposed Rule, Reynolds's survey expert could have tested additional questions in her consumer survey, such as whether the word "causes" is less believable than "can cause." *See supra* p. 36. Because FDA withheld this evidence until after the comment period closed, and then reopened the comment period for just fifteen days, Reynolds's experts could not perform this analysis.

D. The Rule Violates The Tobacco Control Act.

The Rule violates the Tobacco Control Act in two different ways. *First*, the Rule deleted seven of the Act's textual warnings, and added nine FDA-created warnings. *Second*, the Rule increased the total number of graphic warnings to eleven. FDA lacks the authority to take either action.

The Tobacco Control Act adopted two subsections that, together, govern FDA's ability to adjust the Act's warning statements:

> **Section 201(a) Graphic label statements**
>
> … [T]he Secretary shall issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1). The Secretary may adjust the type size, text and format of the label statements specified in subsections (a)(2) and (b)(2) as the Secretary determines appropriate so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area.
>
> **Section 202(b) Change in required statements**
>
> The Secretary through a rulemaking conducted under section 553 of Title 5 may adjust the format, type size, color graphics, and text of any of the label requirements, … if the Secretary finds that such a change would promote greater public understanding of

the risks associated with the use of tobacco products.

15 U.S.C. § 1333(d)[1], (d)[2].

As the text of Section 201(a) plainly says, FDA must "issue regulations that require color graphics depicting the negative health consequences of smoking *to accompany* the label statements specified in subsection (a)(1)." *Id.* § 201(a) (emphasis added). The word "accompany" means "to go with as an associate or companion." Merriam-Webster, *Collegiate Dictionary* 8 (11th ed. 2014). Thus, FDA has an obligation to create color graphics that "go with" the Act's warning statements, unless another portion of the statute allows FDA to change those statements.

Section 202(b) does not allow FDA to re-write the Act's textual warnings. To the extent that this subsection allows FDA to modify the Act's textual warnings, it allows FDA to do so only *after* FDA has issued a valid graphic-warnings rule and the textual warnings contemplated by the Act have taken effect. This conclusion follows from the Act's text, structure, and purpose.

The text of Section 202(b) allows FDA to "adjust the format, type size, color graphics, and text of any of the label requirements." 15 U.S.C. § 1333(d)[2] (emphasis added). The ability to adjust the "color graphics" shows that Section 202(b) applies only after FDA has issued a valid graphic-warnings rule—if FDA had not done so, there would be no color graphics to adjust.

Structurally, Section 201(a) begins by telling FDA to issue a graphic-warnings rule. Then, in the very next sentence, Section 201(a) tells FDA what type of modifications it can make to the textual warnings in that rulemaking: namely, changes that are necessary to make sure that the warnings are "clear, conspicuous, legible and appear within the specified area." *Id.* § 1333(d)[1]. Finally, the *next subsection* as codified—Section 202(b)—gives FDA a greater ability to adjust the textual warnings. This structure demonstrates Congress's plan: *Before* FDA issues the graphic-warnings rule required by Section 201(a), it can use the authority in Section 201(a) to make minor adjustments to the textual warnings. *After* FDA issues that rule, however, Section 201(a) is no longer relevant, and FDA can use

Section 202(b)'s broader authority. *See* Antonin Scalia & Bryan A. Garner, *Reading Law* 156 (2012) ("Material within an indented subpart relates only to that subpart[.]").

FDA's contrary argument—that it can bypass the narrower provision in Section 201(a) and go straight to the broader provision in Section 202(b)—would contravene the statutory structure. Indeed, FDA's view would render the narrower modification provision superfluous, thus violating a cardinal interpretive principle. *See Corley v. United States*, 556 U.S. 303, 314 (2009).

The Act's purpose further demonstrates that FDA cannot rely on the broader authority in Section 202(b) until after the Agency has issued a valid graphic-warnings rule. If FDA could rely on that provision before issuing a rule, then the Agency could delete *all* of the Act's textual warnings and write its own. If Congress had wanted FDA to do that, however, then Congress would not have bothered to include nine textual warnings in the Act. Instead, Congress would have simply directed FDA to "issue regulations that require [warning statements and] color graphics." 15 U.S.C. § 1333(d)[1]. But that is not what Congress did.

FDA also violated the Act by changing the total number of warnings from nine to eleven. As noted above, Section 202(b) empowers FDA to "adjust the format, type size, color graphics, and text" of the warnings. *Id.* § 1333(d)[2]. Nothing in the statute, however, allows FDA to create *additional* warnings. If Congress had intended to authorize FDA to do that, it would have done so expressly, as it has done elsewhere in the Food, Drug, and Cosmetic Act. *See* 21 U.S.C. § 343(q)(2)(A).

E. Under The Act, No Changes To Cigarette Packages Or Advertising May Take Effect Until 15 Months After The Issuance Of A *Valid* Rule.

The Tobacco Control Act tied the effective dates of the new textual warnings and several related labeling requirements to the effective date of a graphic-warnings rule. *See* Pub. L. No. 111-31, § 201(b) (setting effective date for the textual and graphic warnings in 15 U.S.C. § 1333); *id.* § 103(q)(5) (using identical text to set effective date for related requirements in 21 U.S.C. § 387c(a)(2)); *id.* § 301 (using identical text to set effective date for related requirement in 21 U.S.C. § 387t(a)). Congress's use

of a single implementation date for the graphic-warnings rule, textual warnings, and related requirements demonstrates an intent that manufacturers not be subjected to multiple, costly overhauls of their packages and advertising. Because the Rule is legally invalid, the Court should order that the textual warnings and related requirements cannot take effect until fifteen months after FDA issues a legally valid rule. *See* Order, *R.J. Reynolds Tobacco Co. v. FDA*, No. 11-1482 (D.D.C. Feb. 29, 2012).

II. PLAINTIFFS ARE ALSO ENTITLED TO A PRELIMINARY INJUNCTION.

Pending its ruling on the merits, the Court should preliminarily enjoin the Rule and postpone its effective date until fifteen months after Plaintiffs' claims are resolved. The APA provides that, "[o]n such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court … may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705. Under section 705, the Court must consider the same factors that govern injunctive relief under Federal Rule of Civil Procedure 65. *Texas v. United States*, 95 F. Supp. 3d 965, 973 (N.D. Tex. 2015). Those factors are whether (1) the plaintiff is likely to succeed on the merits; (2) the plaintiff will suffer irreparable harm in the absence of an injunction; (3) the injunction will not substantially injure other interested parties; and (4) the injunction would further the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). As discussed, Plaintiffs are likely to succeed on the merits. *See supra* Part I. Because Plaintiffs also satisfy the remaining factors, injunctive relief is appropriate.[12]

A. Plaintiffs Will Suffer Irreparable Harm Absent A Preliminary Injunction.

Without a preliminary injunction, Plaintiffs will suffer irreparable harm. As the Fifth Circuit has "repeatedly held, … the loss of First Amendment freedoms for even minimal periods of time

[12] As noted above, the Tobacco Control Act tied the effective dates of the new textual warnings and several related labeling requirements to the effective date of a graphic-warnings rule. *See supra* Part I.E. A preliminary injunction that delays the Rule's effective date would therefore delay these other requirements as well.

constitutes irreparable injury justifying the grant of a preliminary injunction." *Texans for Free Enter. v. Tex. Ethics Comm'n*, 732 F.3d 535, 539 (5th Cir. 2013) (brackets and quotation marks omitted); *accord Elrod v. Burns*, 427 U.S. 347, 373 (1976) (plurality op.); *R.J. Reynolds Tobacco Co.,* 823 F. Supp. 2d at 50. Because the Rule violates the First Amendment, Plaintiffs will be irreparably harmed by it. In particular, Plaintiffs will be required to engage in compelled speech as a condition of continuing to operate their businesses of manufacturing and/or selling cigarettes. *See* Huckabee Decl. ¶¶ 5, 8, 15–16, Reed Decl. ¶¶ 5, 7, 15–16; Wall Decl. ¶¶ 5, 13, 24, 28; Erkin Decl. ¶¶ 4–7; Ismail Decl. ¶¶ 7–10.

In addition, the loss of First Amendment freedoms here will cause Plaintiffs direct economic harm. The graphic warnings will undermine the ability of the Manufacturer Plaintiffs to communicate truthful messages to adult cigarette consumers, thereby also undermining their ability to convince adult consumers currently choosing their competitors' brands to switch. *See* Huckabee Decl. ¶¶ 5, 12, 15; Reed Decl. ¶¶ 5, 17; Wall Decl. ¶¶ 5–6. The graphic warnings will also cause the Retailer Plaintiffs to lose business from smokers, non-smokers, or both. If the Retailer Plaintiffs choose to display cigarette packages and advertising, non-smokers will be more likely to shop in stores that do not display those packages and advertising, and thus do not contain these offensive images. If the Retailer Plaintiffs stop displaying cigarette packages and advertising after the Rule takes effect, smokers will be more likely to shop in stores that do display those packages and advertising. Either way, the Retailer Plaintiffs are likely to suffer financial harm. Erkin Decl. ¶¶ 8–10; Ismail Decl. ¶¶ 11–13.

Although the Rule's effective date has been postponed to October 16, 2021, a preliminary injunction is needed now. The Manufacturer Plaintiffs cannot implement the Rule's requirements without extensive advance preparation and expenditures. Congress and FDA recognized as much by providing a fifteen-month implementation period. *See* Pub. L. No. 111-31, § 201(b); 85 Fed. Reg. at 15,694; *see also* Cost-Benefit Analysis at 24 ("a labeling change requires a minimum of 15 months to fully implement"). For example, the Rule states that "FDA strongly encourages entities to submit their

cigarette plans as soon as possible after publication of [the Rule]." 85 Fed. Reg. at 15,699. The specified plans must include information about each company's proposed revised packaging and each manufacturer's plan for ensuring that the warnings are randomly displayed and distributed. *Id.* Developing such plans, particularly on the expedited timeline "strongly encourage[d]" by FDA, will require the Manufacturer Plaintiffs to incur significant expense and substantial business disruption very early on in the compliance process and in fact, the Manufacturer Plaintiffs have already begun expending significant human capital and funds to this end.

At the same time, the Manufacturer Plaintiffs cannot risk disregarding the Rule until there is greater legal certainty about its validity. As a practical matter, this means that they cannot wait for this Court to rule on a summary judgment motion before beginning to prepare their new packages and advertisements. Plaintiffs must therefore plan two versions of every advertisement: one that complies with the rule and one that does not. In short, absent a preliminary injunction, the Manufacturer Plaintiffs will be forced to spend millions of dollars and thousands of employee-hours to comply with a regulation despite the substantial chance that it is legally invalid. These costs are detailed at greater length in the accompanying affidavits, but they are considerable. For example:

- Reynolds and Santa Fe would be forced to modify approximately 390 individual package designs. Decl. of Lamar W. Huckabee ("Huckabee Decl.") ¶ 8.

- The Rule requires that all eleven warnings be "randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed." 85 Fed. Reg. at 15,709 (codified at 21 C.F.R. § 1141.10(g)(1)). Reynolds and Santa Fe employees have already spent more than 1,000 hours working to comply with this requirement. Huckabee Decl. ¶ 10.

- Reynolds and Santa Fe will need to purchase approximately 6,000 printing cylinder bases and additional tools to print the redesigned packages. *Id.* ¶ 11. Reynolds and Santa Fe will then need to have the cylinders engraved so they can be used to apply the ink on the new cigarette packages. *Id.* The costs of the cylinders, tools, and engraving is expected to exceed $15 million. *Id.* The work to engrave the cylinders will take several months and must begin within ten months after the Rule is published. *Id.*

- Reynolds and Santa Fe will need to hire a graphics design firm to design the new labeling. This design work will cost at least $1 million and take several months, and approximately 3,000 hours of employee and supplier time, to complete. *Id.* ¶ 12.

- Reynolds and Santa Fe will need to begin the extensive internal approval process for the new package designs. *Id.* ¶ 13. This process is expected to require several months, and at least 300 hours of employee time, to complete. *Id.*

- The Rule also requires revised warnings to appear in advertising. Reynolds and Santa Fe will thus need to modify existing brand advertising that appears on their websites and retail point-of-sale advertising. *Id.* ¶ 15. Collectively, Reynolds and Santa Fe will need to redesign, print, and replace point-of-sale advertising at approximately 200,000 retailers. *Id.* These tasks will cost approximately $10 million and involve thousands of hours of employee and supplier time. *Id.*

- In anticipation of the Rule becoming effective, Reynolds and Santa Fe will need to begin manufacturing cigarettes in compliant packaging beginning at least three months prior to the Rule's effective date. If the Rule is then invalidated, Reynolds and Santa Fe will be unable to lawfully sell those cigarettes because they will not carry the correct FDA-mandated warnings and be considered misbranded under the Act. *Id.* ¶ 16. This will cost Reynolds and Santa Fe over $200 million. *Id.*

ITG Brands and Liggett also must bear substantial costs. *See* Reed Decl. ¶¶ 7–16 (describing design, printing, advertising, and administrative costs); Wall Decl. ¶¶ 7–30 (same). Moreover, Liggett, like other smaller cigarette manufacturers, is disproportionately burdened by these costs. *See* Cost-Benefit Analysis at 6. But FDA declined to mitigate the burden on small manufacturers, effectively rubber-stamping the inequitable burdens of implementation. *Id.* at 58-59.

What is more, Plaintiffs' harm will be exacerbated by the COVID-19 pandemic and its effects on business operations. The Manufacturer Plaintiffs will likely have to spend even more time and incur even more costs to make the required changes due to disruptions to their normal business operations. *See* Huckabee Decl. ¶ 17; Reed Decl. ¶ 14; Wall Decl. ¶ 15.

Plaintiffs will not be able to recoup these costs if (as is likely) this Court ultimately concludes that the Rule is unlawful. And economic costs which are not recoverable through compensatory damages constitute irreparable injury. *See, e.g.*, *Texas v. EPA*, 829 F.3d 405, 433–34 (5th Cir. 2016) ("[C]omplying with a regulation later held invalid almost always produces the irreparable harm of

nonrecoverable compliance costs." (quoting *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 220–21 (1994) (Scalia, J., concurring in part and in the judgment)); *Enter. Int'l, Inc. v. Corporacion Estatal Petrolera Ecuatoriana*, 762 F.2d 464, 473 (5th Cir. 1985) ("The absence of an available remedy by which the movant can later recover monetary damages, however, may also be sufficient to show irreparable injury."); *Teladoc, Inc. v. Tex. Med. Bd.*, 112 F. Supp. 3d 529, 543 (W.D. Tex. 2015); *see also R.J. Reynolds Tobacco Co.,* 823 F. Supp. 2d at 50 (finding, in the case challenging FDA's 2011 graphic warnings rule, "irreparable economic injury" where plaintiffs would not be able to recover damages from FDA (citing *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 77 n. 19 (D.D.C. 2010))). Indeed, this Court recognized that Plaintiffs would suffer irreparable harm absent a postponement because they faced "imminent compliance costs" that "would not be reimbursed." May 8, 2020 Order at 1–2; *see id.* at 1 ("the government . . . agrees that plaintiffs would suffer irreparable injury absent a 120-day postponement"). The same logic applies to this motion.

Moreover, the Fifth Circuit has held that expenditures like the ones incurred here constitute irreparable harm even where they occur far in advance of a rule's compliance date. In *Texas v. EPA*, the court found irreparable injury, and granted a stay pending review, where power companies were spending money in 2016 to comply with EPA installation deadlines of 2019 and 2021. 829 F.3d at 416. The Court recognized that the required emissions controls "take several years to install" and "the regulated companies will have to begin installation almost immediately." *Id.* at 433. Likewise, though the effective date of the Rule is still about seventeen months away, the evidence discussed above demonstrates that the Rule requires the Plaintiffs to commence extraordinary compliance measures almost immediately, as the costly changes it requires are ongoing and escalating. Furthermore, as noted above, Plaintiffs expect to face interruptions and delays as a result of COVID-19's impact on business operations, which will require them to begin implementation even sooner. *See supra* p. 62.

This is precisely the situation that 5 U.S.C. § 705 and Rule 65 are intended to prevent. As the

plain text of § 705 provides, a reviewing court should "issue all necessary and appropriate process" in order to "postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings" and should do so "to the extent necessary to prevent irreparable injury." 5 U.S.C. § 705. Here, as explained above, "postpon[ing] the effective date" of the graphic warnings and preserving the status quo is "necessary to prevent irreparable injury." *Id.*

In short, Congress intended that manufacturers have fifteen months to implement all of the Act's new labeling requirements, and that is all that Plaintiffs' preliminary-injunction request is seeking.

B. A Preliminary Injunction Will Not Harm The Interests Of The Government Or The Public.

The balance of harms and the public interest, which are the third and fourth preliminary-injunction factors, "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009); *see also Texas v. United States*, 809 F.3d 134, 187 & n.204 (5th Cir. 2015). Here, both factors together weigh heavily in favor of a preliminary injunction.

While Plaintiffs will incur tens or perhaps hundreds of millions of dollars in unrecoverable costs if preliminary injunctive relief is not granted, FDA cannot show any meaningful harm to itself or to the public from a preliminary injunction. To begin, "injunctions protecting First Amendment freedoms are always in the public interest." *Texans for Free Enter.,* 732 F.3d at 539 (quotation marks omitted); *accord Opulent Life Church v. City of Holly Springs*, 697 F.3d 279, 298 (5th Cir. 2012). The Rule violates the First Amendment, so the public interest strongly favors a preliminary injunction.

Moreover, even if the Court ultimately held that the Rule was lawful, the limited delay would not harm the public interest. *First*, FDA has shown no urgency in issuing the Rule. The D.C. Circuit vacated FDA's 2011 Rule in August 2012. *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012). But FDA waited to issue a second rule until March 2020—a delay of more than *seven and a half years*. FDA cannot now claim that a delay of a few months would harm the public interest.

Second, a short delay would not cause any cigarettes to be sold without adequate warnings. The

existing warnings already reflect the major risks of smoking, including lung cancer, heart disease, and the major risks of smoking during pregnancy. *See* 15 U.S.C. § 1333 (2008). And those warnings will continue to be displayed on *all* cigarette packages and in *all* cigarette advertisements.

Third, FDA effectively concedes an inability to quantify whether the Rule will meaningfully change smoking behavior or beliefs. In the 2011 Rule, FDA determined that graphic warnings would reduce smoking by a mere 0.088%, a number that FDA conceded was statistically indistinguishable from zero. 76 Fed. Reg. at 36,775–76. And in the current Rule, FDA tellingly does not even claim that graphic warnings will reduce smoking. Moreover, FDA's own studies show that the warnings would not have a meaningful effect on the public's beliefs. *See supra* pp. 13–17. Because the Rule would not prevent any material harm to the government's or the public's interests even if implemented permanently, a short delay in its implementation will not meaningfully affect those interests either.

In short, no substantial injury would be caused to FDA or the public by enjoining the Rule for the short period of time necessary to review its legality. In contrast, absent such relief, the Rule will irreparably deprive Plaintiffs of their First Amendment rights and tens of millions of dollars.

CONCLUSION

The Court should grant Plaintiffs' motion for summary judgment and a preliminary injunction; preliminarily enjoin Defendants from enforcing the Rule, the Tobacco Control Act's graphic-warning requirement, and related requirements; declare that the Rule violates the First Amendment, the APA, and the Tobacco Control Act; vacate the Rule in its entirety; declare that the Tobacco Control Act's graphic-warning requirement violates the First Amendment; permanently enjoin Defendants from enforcing the Rule and the Tobacco Control Act's graphic-warning requirement; permanently enjoin Defendants from enforcing the Tobacco Control Act's textual warnings and related requirements until fifteen months after FDA issues a legally valid rule; and declare that Plaintiffs are permitted to continue using their current packaging and advertising until fifteen months after FDA issues a legally valid rule.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 15, 2020, a true and correct copy of the foregoing was electronically filed with the clerk of court for the U.S. District Court for the Eastern District of Texas, using the CM/ECF system, which will send a notice of electronic filing to all counsel of record.

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CERTIFICATE OF CONFERENCE

I hereby certify, pursuant to Local Rule CV-7(i), that (1) I complied with the meet and confer requirement in Local Rule CV-7(h), and (2) this motion is opposed.

I have conducted the personal conference required by Local Rule CV-7(i). Specifically, on April 13, 2020, I, along with Christian G. Vergonis, had a telephone conference with Eric Beckenhauer and Michael H. Baer. In that conference, we discussed this matter, possible agreements regarding a briefing schedule, and the likelihood that Plaintiffs would file motions for summary judgment and a preliminary injunction. We (the same four attorneys) then had additional telephone conversations on April 16, 2020, April 21, 2020, and April 27, 2020. As reflected in the Joint Motion the parties filed on May 6, 2020, the parties reached agreement on several issues, but Defendants remain committed to the Rule and do not concede that Plaintiffs are entitled to a preliminary injunction. *See also* Local Rule CV-7(i)(3) (exempting motions for summary judgment from the "meet and confer" requirement and the "certificate of conference" requirement). Therefore, discussions have conclusively ended in an impasse, leaving an open issue for the Court to resolve.

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